RetCam II

Wide-Field Digital Imaging System

Service Manual
P/N 04-03-023 Rev A

Clarity
medical systems

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1.0
Notices and Labels

Electrical Safety Notices

The RetCam II System has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Model: RetCam II
Manufactured by Clarity Medical Systems, Inc.
dba Massie Laboratories, Inc.
Pleasanton, CA
Made in USA

Class I Type BF Electrical Equipment

Rated for Continuous Operation

IEC 60601-1:1988 + A1:1991 + A2:1995

Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC60950 for data processing equipment and IEC 60601-1-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical services department or your local representative

WARNING: This equipment should be connected using the power cord supplied by Clarity.

WARNING: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RetCam II uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RetCam II is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes., provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the RetCam II or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The RetCam II is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Not all of the required testing met the full limits of IEC61000-4-4. Refer to Important User Safety Notices on page 22 for further information.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RetCam II requires continued operation during power mains interruptions, it is recommended that the RetCam II be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	80-2500 MHz, 3/m, 80% 1 KHz AM	3 V/m	

WARNING: Interference may occur in the vicinity of equipment marked with this symbol. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Input and Fuse

120/230V~

50/60 Hz, 750VA

Only for North American Systems:

3AG 10A 250V

Only for International Systems:

3AG TIME DELAY 5A 250V

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Safety Information

This medical equipment is in compliance with UL60601-1/CAN/CSA C22.2 No.601.1-S6LK

European Authorized Representative address

EC REP

MediMark® Europe Sarl. 11, rue Emile Zola. BP 2332F-38033 Grenoble Cedex 2. FranceTel: +33 (0)4 76 88 43 22 Fax: +33 (0) 4 76 17 19 82e-mail: Info@medimark-europe.com

FDA (USA) Notices

This device is listed with the United States of America (USA) Food and Drug Administration (FDA) for commercial distribution.

Device Trade Name	RetCam II
Product Code	86 HKI
Classification Name	Ophthalmic Camera
Classification Regulation Number	886.1120
Medical Device Classification	Risk Class II

Important User Safety Notices

1. Remove the lens and store it in the lens box and secure the handpiece in its storage compartment inside the cart before moving the cart to a new site.

2. Carefully inspect and clean the lens piece before each use. DO NOT use if the front lens of the lens piece is nicked or scratched.

3. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.

4. Unauthorized modifications or additions to the software or hardware of the system will void the warranty and could adversely affect the system function.

5. DO NOT AUTOCLAVE any part of the device. Refer to the Chapter on Maintenance and Support for cleaning recommendations.

6. Do not use the white light source for longer than 5 cumulative minutes on the same eye during an exam.

7. Appropriately power down and unplug the unit and allow the light source bulb to cool before replacing it. Refer to the instructions to Replace Illumination Lamp as necessary.

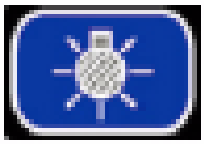
8. Never connect the RetCam II to a network or any externally powered devices or peripherals during imaging.

9. Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.

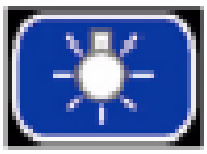
10. The RetCam II is for use by or on the order of a health care professional.

11. It is possible that during Electrical Fast Transients from the AC line, the system's display may scroll continuously. This is an indication that the source of AC power has electronic disturbance (transients). If this indication is present, imaging should not proceed until the disturbance has ceased: the AC plug is put into a different AC outlet: or RetCam II is run from the UPS. If the disturbance persists, an error message may be displayed, which then may require a system reset. Toe perform a system reset, press the (I/O) power switch on the control panel for approx 6 seconds until the system powers down, then press the (I/O) button again to power the system back on . THIS DOES NOT PRESENT A SAFETY RISK TO THE PATIENT, USER, OR ENVIRONMENT

Labels and Symbols



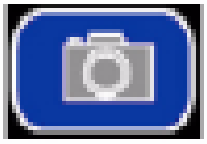
Decrease lamp Intensity



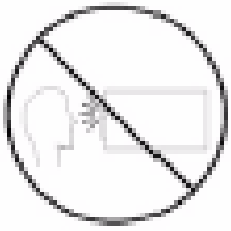
Increase lamp Intensity

Focus nearer

Focus away



Snap switch

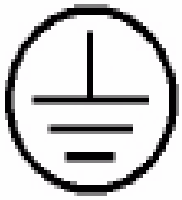


CAUTION:
DO NOT LOOK
DIRECTLY INTO
LIGHT SOURCE

BEFORE CONNECTING
READ INSTRUCTIONS

CAUTION – ELECTRICAL HAZARD
HIGH VOLTAGE IN THE FA UNIT

No user service recommended. Refer FA servicing to qualified Clarity personnel.



Protective earth (ground)

FA Intensity, Increase clockwise

(FA = Flouresceln angiography)

FA light on

FA switch

FA light standby

FA light on

FA light standby

Alternating current (AC)

This symbol next to the USB connection indicates that the USB connection is intended only for USB memory sticks. This symbol on the Clarity mains label indicates that the fuse used should be matched with the input voltage.

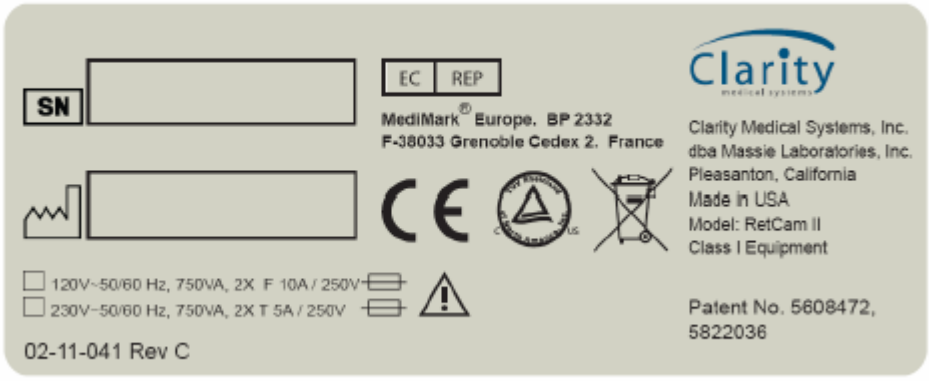
Type BF Equipment

Do not use if dropped

Clean lens piece after use

Separate collection of waste at end-of-life as required by European directives.

Product Label



2.0
Introduction

The **RetCam II Wide Field Imaging System** (system) is designed using state-of-the-art digital technology to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

The system is designed for easy use and operation by either a physician or trained staff members. High resolution digital images and videos can be quickly captured, stored, displayed for review, transferred and/or printed by simply using the trackball to point and click.

The system as delivered is intended for use indoors, at normal room temperatures (59º F to 95º F or 15º C to 35º C), non-condensing humidity range 25% to 93%, upright, on a level surface, with the front casters locked and the dust cover off for proper ventilation.

This manual contains maintenance instructions, specifications and service instructions.

Note:

Only those modules identified within this service manual are "authorized" for repair by the customer. Any service outside the scope of this manual shall void the warranty and may compromise the safety/efficacy of the system.

This manual is meant to be used in conjunction with the RetCam II User's Manual.

The supplier will make available on request, component part lists, descriptions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated by the manufacturer as repairable.

CAUTION: Use of this manual is intended for qualified technical personnel only. If in doubt, please contact the manufacturer before proceeding.

Storage and Transport

Note: Always return the handpiece to the holster on the top surface when not imaging. The handpiece cable can be draped over the side support, but do not wrap it tightly or damage to the fiber optic may result.

For storage of the system when not in use, disconnect the power cord and store it in the drawer. Remove all loose objects from the top surface. Fold the display down flat. Wipe down the surfaces with a soft cloth. Place the dust cover over the system. Lock the casters to keep it in place.

The system is provided with the means to easily move it between operations or between beds in the NICU while it is running. To relocate the system while it is running, disconnect the power cord at both ends, release the front caster locks and gently roll the system to the new location. The internal power supply will keep the computer and monitor running for several minutes. Once in the new position, lock the casters, reconnect the power cord at both ends and continue with imaging. If the floor is uneven or tiled surface, move the system carefully to avoid damage from excessive vibration.

The system is not intended to be transported outdoors from building to building. For information on how to safely transport the system out of doors or in anything but an upright position, please contact Customer Service. The RetCam II has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended. Inspection and testing of the system by a factory-trained technician after transport outdoors or in a non-upright configuration is necessary to insure continued compliance with all safety standards.

System Description

The RetCam II system consists of several modules mounted in a stable, high quality integrated mobile cart for easy, safe transportation from one location to another. The front pair of lockable casters allow for easy maneuverability and positioning, while the fixed rear wheels guide the unit in a straight line during transport. (Ref. Figures 1 and 2)

1) Display: A high resolution LCD flat panel display is standard with the system.

2) Control Panel: A membrane control panel turns the system on with one button, and has controls for illumination intensity, camera focus and snap (capture an image or start/stop video recording).

3) Handpiece: The handpiece contains the actual 3-chip CCD. It is light weight and easy to use. The front lens pieces are removable, and allow quick and easy exchange.

4) Interconnect Cable: The interconnect harness contains three separate cables, the fiber optic for transmission of illumination light, the camera cable, and the focus motor control cable.

5) Light Box: The light box contains a CCD camera control unit, a halogen illumination light, and the control circuitry for light intensity, focus, image capture and system logic.

6) Computer: The computer is controlled by a keyboard and trackball. It is a Pentium4 based system, running a specialized Embedded Windows XP, with two internal DVD storage drives and media and proprietary software. The system has an integrated network adapter, and USB hub.

7) Uninterruptible Power Supply (UPS): The computer, display and optional image printer are powered by an Uninterruptible Power Supply. The UPS helps to protect against accidental loss of images due to power surges or sudden power loss.

The UPS can store enough energy to power the computer and display for several minutes allowing the system to be unplugged from the electrical outlet and moved from room to room or bed to bed without having to reboot the system.

8) Footswitch: The footswitch is a rocker style unit with a function switch on each side, and a push button in the middle.

   The pedal on the left side controls focusing. Rock this pedal to the left to focus closer, and to the right to focus more distant.

   The pedal on the right controls illumination light intensity. Rock this pedal to the left to decrease intensity and to the right to increase intensity.

   The push button in the middle is called the snap switch. An image is captured and stored each time the snap switch is depressed. In video mode, this switch can be used to alternately start and stop video recording.

9) Power Conditioner: The power conditioner isolates the RetCam system from power/line disturbance and meets medical electrical device safety requirements.

10) Storage Drawer(s): One storage drawer is supplied on all units for lens pieces, DVD-RAM's and accessories. Without the Fluorescein Angiography light source, an additional drawer is furnished for extra storage.

11) Report Printer (option): A high resolution inkjet printer can print reports on 8.5" x 11" paper.

12) Image Printer (option): The high quality Mitsubishi dye-sublimation printer can print single images of 3.75" x 4.75" or two images one above the other in a smaller size.

13) Fluorescein Angiography Source (option): A blue exciter light source is available complete with green barrier filter for the handpiece for doing F.A. digital photography with the RetCam II.

Figure 1 RetCam II

Fig 2 Handpiece and Lens

Figure 3 Lens Piece Selection

Lens Model	Application	Common Field of View
D1300	RCP & Anterior Segment	130 Degrees
B1200	Children's & Anterior Segment	120 Degrees
E800	High Contrast Children's & Adults	80 Degrees
C300	High Magnification	30 Degrees
PL100	Portrait Lens	N/A

Fig 3 Lens Piece Selection

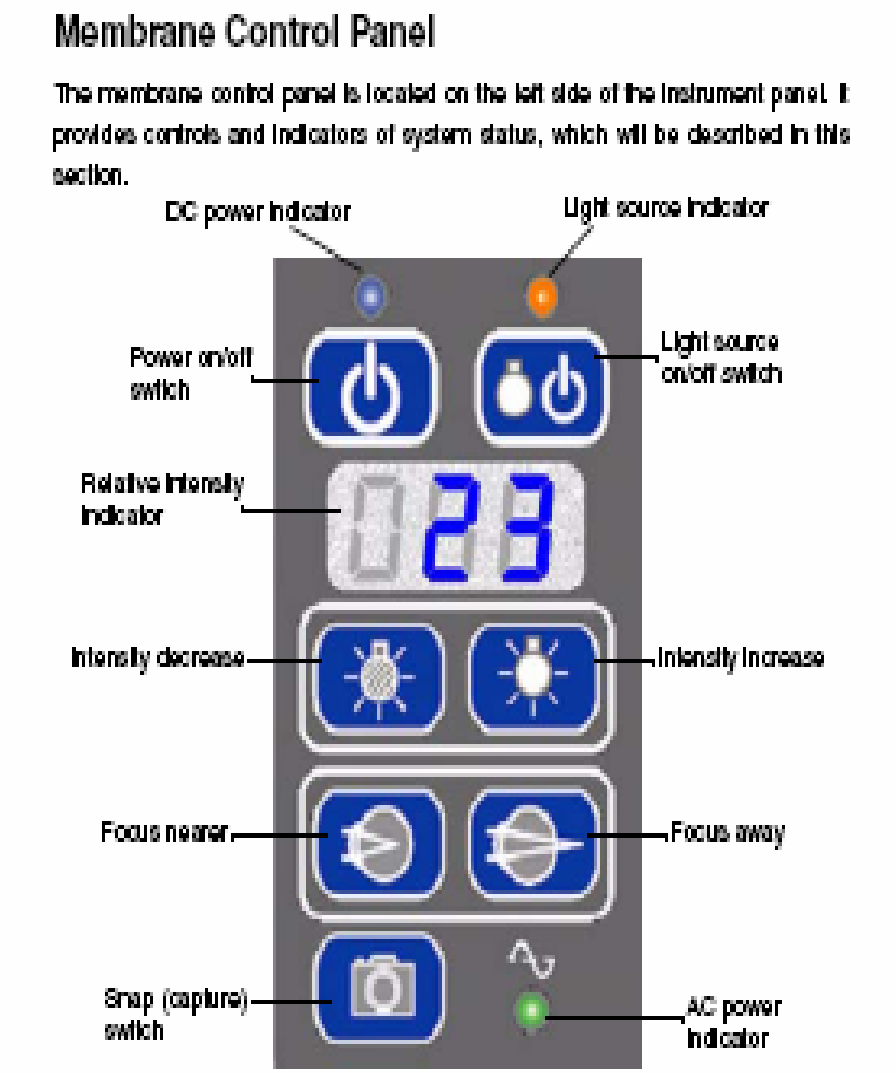

Membrane Control Panel
The membrane control panel is located on the left side of the instrument panel. It provides controls and indicators of system status, which will be described in this section.
DC power indicator
Light source indicator
Power on/off switch
Light source on/off switch
Relative Intensity Indicator
23
Intensity decrease
Intensity increase
Focus nearer
Focus away
Snap (capture) switch
AC power indicator

Fig 4 Membrane Control Panel

3.0
Maintenance

3.1 Recommended Maintenance Schedule

Between patients: clean and inspect lens piece.
Daily: Back up data to a network
Weekly: Wipe down the system.
Monthly: Inspect cables and connections for wear.
Annually: Vacuum the air inlet screens in the rear of the base

Burned out bulb: Replace illumination bulb
Blown fuse: Replace system fuses
Continuously beeping UPS: Replace UPS

3.2 Cleaning Procedures

For cleaning purposes, the RetCam II is divided into two categories:

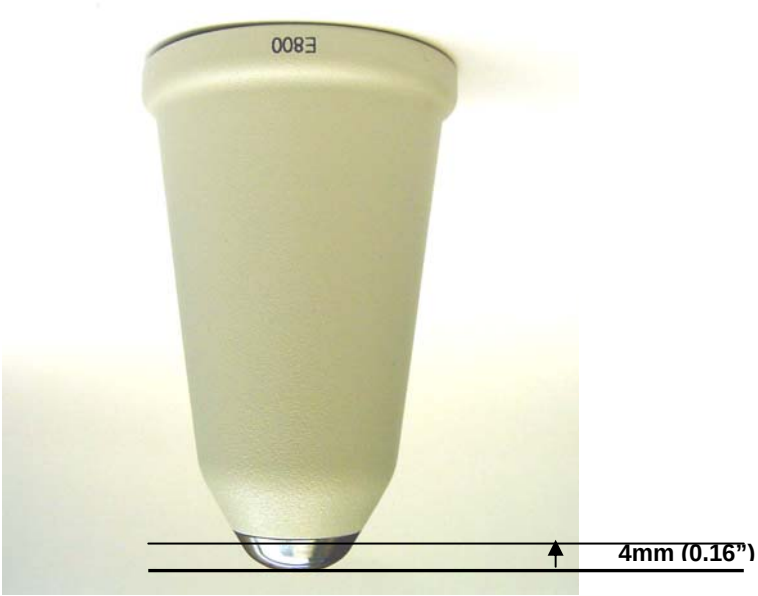
1. The Lens Piece that contacts the patient
2. The rest of the system

3.2.1 The Lens Piece

The Lens Piece should be cleaned thoroughly between patients to prevent the spread of infectious disease. As recommended by the American Academy of Ophthalmology, the cleaning liquid of choice is 70% isopropyl alcohol. Moisten a clean towelette with the solution and use a gentle wiping action across the front of the lens piece, being sure to pay special attention to the concave contact lens area. To prevent irritation to the next patient from residue left on the lens, rinse the tip of the lens piece thoroughly with disinfected distilled water.

Warning: To avoid damage, do not autoclave any part of the RetCam II system.

The American Academy of Ophthalmology also recommends disinfecting with 1:10 dilution of bleach for 5 minutes.(refer to page inserts following this page). .



Immersion to only 4 mm

Fig 5 Lens Tip cleaning

WARNING: To handle chemicals safely, consult Material Safety Data Sheets (MSDS) before using isopropyl alcohol or bleach.

Note: If you disinfect with bleach, you must rinse the frontmost part of the lens piece with disinfected distilled water, and make sure the lens piece is wiped completely clean before using on a patient.

Note: Never immerse the entire lens piece or handpiece in any liquid or solution. For disinfection purposes, you can Immerse no more than 4mm (about 1/16") of the tip of the lens piece. In an inverted position. FOR NO MORE THAN 15 MINUTES. Immersing more or longer than this causes corrosion of the lens piece and voids the lens warranty. Use water, bleach, 3% hydrogen peroxide or isopropyl alcohol. Permissible immersion depth is illustrated in the Figure above. It is important not to immerse the join where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

3.2.2 System Cleaning.

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions directly on the computer or other module, spray the cloth instead. The cart and side panels can be sprayed with a mild soap and/or water solution if care is taken not to introduce the mist into the modules.

The lens piece should be checked before each use for damage to the front contact lens and surrounding surface. The interconnect cable and connectors should be checked for damage to the end connectors and protective covers.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient's eye.

3.2.3 **AAO Bloodborne Pathogen Information**

Information Statement

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Minimizing Transmission of Bloodborne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms

Introduction

This document is intended to provide guidance to ophthalmologists and their staff about minimizing transmission of infection in their offices and operating rooms. This document addresses prevention of bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and other viruses, such as adenovirus and herpes simplex virus. These recommendations are mainly based on broad guidelines issued by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Labor for health care workers.

Bloodborne pathogens may be present in blood, blood-contaminated products or other bodily fluids especially if contaminated with or mixed with blood. Percutaneous injuries (e.g., a needlestick or cut with a sharp object) represent the greatest risk of transmission of bloodborne pathogens to health care workers. Universal precautions apply to blood and other body fluids containing visible blood, but not to tears unless they contain visible blood.[1] The use of universal precautions, including handwashing and barriers, reduces contact with blood and bodily fluids, thus reducing exposure of health care workers to bloodborne pathogens. The use of safety devices and techniques to reduce handling of sharp instruments also reduces the number of percutaneous injuries.

Exposure to HIV in health care settings has been of major concern. As of June, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 56 U.S. health care personnel with HIV transmission associated with occupational exposure, and another 138 reports of possible transmission to date.[2] For health care personnel exposed through percutaneous means to HIV-infected blood, the estimated risk for HIV infection is 0.3%.[2] Risks associated with a mucous membrane exposure are estimated to be 0.09%.[2] Risks for HIV seroconversion after a percutaneous exposure have been found higher for those exposed to a larger quantity of blood, (i.e., a device visibly contaminated with blood, a needle being placed directly in a vein or artery, or a deep injury) or when the source patient was terminally ill with AIDS.[2]

Transmission of HBV poses a risk to health care workers. In 1994, approximately 1,000 health care workers were infected with HBV from occupational exposure.[2] Since implementation of routine preexposure vaccination of health care personnel and precautions to prevent exposure to blood, there has been a significant decrease in HBV infection among health care personnel.[2] HBV is transmitted by mucosal or percutaneous exposure to blood and serum-derived body fluids from persons with acute or chronic infection. The risk of developing clinical hepatitis from exposure to the blood that was both hepatitis B surface antigen (HbsAg) and hepatitis E antigen (HbeAg) positive was 22 to 31%.[2] Any person who is seropositive for hepatitis B surface antigen can be infectious. The CDC recommends that health care personnel who have routine contact with blood and bodily fluids be vaccinated.[3] For applicable settings, the OSHA standard requires that hepatitis B vaccine be made available to personnel with occupational exposure to blood, at the employer's expense.[4]

American Academy of Ophthalmology®
P.O. Box 7424
San Francisco, CA 94120-7424
415.561.8500
http://aao.org

HCV is the cause of most parenterally transmitted cases of non-A, non-B hepatitis in the U.S. There is no vaccine currently available and postexposure prophylaxis has not appeared effective in preventing infection. HCV is thought to be transmitted relatively rarely through occupational exposure to blood.[2] The incidence of seroconversion after percutaneous exposure to an HCV-positive source is estimated to be 1.8%.[2] Hepatitis C virus (HCV) has been isolated in tears and aqueous humor.

Adenovirus has been the main cause of nosocomial outbreaks of conjunctivitis. These outbreaks have mostly occurred in eye clinics or offices. Adenovirus can survive for long periods on environmental surfaces and ophthalmic instruments can become contaminated and transmit infection. Handwashing, glove use and disinfection of instruments can all help to prevent or limit the transmission of adenovirus. Infected personnel should not provide patient care for the duration of symptoms after onset of adenoviral conjunctivitis

Background

The National Society to Prevent Blindness, in cooperation with the American Academy of Ophthalmology assembled a Task Force to examine the risk of acquiring HIV infection in the course of eye examinations and treatments. The Task Force helped develop precautions to reduce spread of pathogens that might be present in tears.[5]

In August 1987, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for the prevention of HIV transmission in a health-care setting.[6] This was followed two months later by a joint advisory notice from the U.S. Department of Labor and the U.S. Department of Health and Human Services regarding the protection against occupational exposure to HBV and HIV.[7] These documents addressed the risk that health care workers may face in the course of their duties and made broad recommendations labelled universal precautions that all health care workers should follow. Neither document distinguished the risks and needs of healthcare workers in ophthalmology from any other health care occupation.

In June 1988, the CDC further clarified their recommendations, particularly as they relate to the protection of health care workers, by stressing the far greater risk of bloodborne viral infections (e.g., HIV and HBV) posed by blood and blood-contaminated bodily fluids than by such bodily secretions as tears.[8] In that document, they noted that "Universal precautions do not apply to ... nasal secretions, sputum, sweat, tears... unless they contain visible blood." Thus, normal tear exposure does not require bloodborne pathogen precautions. In June, 2001, the U.S. Public Health Services updated recommendations for the management of occupational exposures to HBV, HCV and HIV.[2]

In March 1992, the Occupational Safety and Health Administration (OSHA), issued a set of regulations entitled, "Occupational Exposure to Bloodborne Pathogens, "which requires that employers establish safeguards which protect workers against hazards related to bloodborne pathogens.[4] These regulations require identification of who is at risk of occupational exposure, the communication of hazards to employees at risk for exposure, exposure prevention control measures, and what to do if an exposure occurs. In April 2001, the Needlestick Safety and Prevention Act became effective, revising the bloodborne pathogens standard to require employers identify and make use of safer medical devices which can be used to reduce worker exposure.[9]

In 1992, the American Academy of Ophthalmology Public Health Committee developed updated recommendations for ophthalmic practice in relation to HIV.[10] The Committee noted that there were two distinct areas of concern to ophthalmic medical personnel and patients:

1. Transmission of ocular surface infectious agents such as adenovirus or herpes virus. Prevention of transmission of these pathogens requires good hygienic techniques, such as routine hand washing, tonometry cleaning and trial contact lens disinfection.

2. Transmission of bloodborne pathogens such as HIV or HBV. Prevention of transmission of these agents requires the use of bloodborne pathogen precautions, which include the proper use of gloves, needle disposal and other precautions such as administering hepatitis B vaccine in workers exposed to bloodborne pathogens.

Recommendations

The Committee recommended specific measures that would provide adequate protection for the patient, for health care workers in the ophthalmic care setting, and for the ophthalmologist. This document updates four areas:

- Procedures for protection of the patient
- Procedures for protection of the staff
- Procedures for protection of the ophthalmologist
- Responsibilities toward patients with known or suspected HIV infection

I. Procedures for Protection of the Patient

Protection of patients from exposure to the HIV during examination and treatment of eye disorders incorporates

the application of good public health principles and specialized precautions. Since the infection was first recognized in 1981, there has been no evidence to indicate that the HIV has been transmitted through any of the diagnostic or surgical procedures performed by ophthalmologists. According to the CDC, the likelihood of transmission through contact with tears is extremely remote.[8] However, because the virus is potentially lethal, is present in surface epithelia in the eye and in low titers in tears and ocular fluids of infected individuals, and can (in theory at least) be transmitted through mucous membranes, public health officials have recommended that reasonable precautions be taken. Furthermore, because many HIV carriers may be unaware of their infection and show no sign of the disease, the following recommendations should be routinely used for **all** patients. Recommendations for the safe usage of ophthalmic instruments and contact lenses are provided. These guidelines represent good, general ophthalmic technique, because they reduce the risk of transmitting both bloodborne pathogens (HIV, HBV and HCV) and surface infectious agents (e.g., herpes simplex virus, adenovirus, etc.) likely to be encountered in patients presenting for eye examinations.

Recommendations

A. Handwashing.

Handwashing represents the single most effective means of avoiding the risk of transmitting or acquiring infections in the course of examination.[11] The CDC recommends that ophthalmic medical personnel performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients.[5] Handwashing should be encouraged when there is any doubt about the necessity for doing so. For routine handwashing, a vigorous rubbing together of all surfaces of the lathered hands is recommended for at least 10 seconds, followed by a thorough rinsing under a stream of water.[11] Plain soap can be used for handwashing for most routine activities. Gloves may be used as an extra margin of safety. When gloves are worn, handwashing is still recommended because gloves can become perforated and bacteria can grow rapidly on gloved hands. If there are cuts, scratches, or dermatological lesions (e.g., weeping lesions) on the hands, then use of gloves is advisable.

B. Eyedrops.

The bottle tip should not come into direct contact with the patient's tears or conjunctiva. If the tip does touch the patient, the bottle should be discarded.

C. Gowns, masks and protective eye wear.

Gowns, masks and protective eyewear are unnecessary for the usual ophthalmic examination.

D. Disinfection procedures.

Disinfection is a process to eliminate most or all pathogenic microorganisms from inanimate objects, such as medical devices or equipment.[12] This is usually performed using chemicals known as germicides or disinfectants. High-level disinfection kills all organisms and is performed suing a germicide which is regulated by the Food and Drug Administration. The CDC recommends that if there are questions about high-level disinfectants or how to disinfect a particular medical device, the office should contact the manufacturer of the product.[13]

The CDC has recommended the following, which are proven to inactivate infectious HIV, herpes simplex virus, and adenovirus.[5]

- Wiping clean and then disinfecting with bleach is recommended by the CDC as an effective way to inactivate HIV. Remove the entire prism from the tonometer and place it in a suitable receptacle that allows the applanating surface and adjacent 2–3 mm of the tonometer to be immersed in a 1:10 dilution of household bleach (sodium hypochlorite). One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution.[14] After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used while the other is being disinfected. Soaking the entire tip may eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach with a 5 to 10 minute exposure to a fresh solution of either 3% hydrogen peroxide, 70% ethanol, or 70% isopropanol can be followed. These solutions need to be changed at least twice daily.

Goldmann-type Tonometers

A recent study compared several methods of disinfecting Goldmann tonometer tips, which were inoculated with hepatitis C virus.[15] The methods that resulted in the greatest decrease in concentration of HCV RNA were a 5-minute soak in 3% hydrogen peroxide or 70% isopropyl

alcohol following by washing in cold water. A 5-second 70% isopropyl alcohol wipe was not as effective, and a 5-second wipe with povidone iodine was more effective than the isopropyl alcohol wipe in reducing HCV RNA.

The washes are important to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Schiotz Tonometer

The tonometer should be dissembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry) and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Non-contact Tonometers

The non-contact tonometer may not make contact with the cornea or tears, but may cause micro-aerosol formation. The front surface may be wiped with an alcohol-soaked sponge since it may occasionally touch the eye.

Digital Pneumotonometer

Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again. It is important to allow the alcohol to evaporate completely to avoid damage to the corneal epithelium.

Diagnostic Contact Lenses (Goldmann, etc.)

The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens are then vigorously wiped with an alcohol sponge
As an alternative, the inner cup may be filled to the rim or partly immersed within a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface of the lens as well as the contact portion without exposing the anti-reflective coating on the operator surface of the contact lens to the bleach. It is important to rinse to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Other Instruments That May Come Into Contact With Patients

The HIV is a fragile virus and there is no evidence of casual spread from surfaces of ophthalmic instruments. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and, thus, could conceivably be transmitted to other patients.[16] Therefore, if an instrument, such as a slit lamp biomicroscope, has been used for a patient who is suspected of having an ocular infectious disease, it is strongly recommended that the surfaces on the instrument be cleaned with alcohol or bleach.

Trial Fitting Contact Lenses

Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using a hydrogen peroxide or a chlorhexidene-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.[5]

E. Tissue Transplantation.

The Eye Bank Association of America has strict criteria in place to screen corneal and scleral tissue for transplantation, to prevent transmission of diseases. There have been no confirmed cases of occupational transmission of transmissible spongiform encephalopathies, such as Creutzfeld-Jakob disease. The CDC recommends use of stringent chemical and autoclave sterilization methods for heat-resistant instruments that come into contact with high infectivity tissues in patients with suspected or confirmed CJD.[17] For infection control of transmissible spongiform encephalopathies, the World Health Organization recommends the following in situations where there is contact with high infectivity tissues in patients with suspected or confirmed CJD:[18]

1. Use single-use surgical instruments
2. Avoid mixing instruments used on tissues of high infectivity vs. no infectivity
3. Destroy re-usable instruments, where possible
4. If destruction is not possible, decontaminate instruments.

The Risk of Acquiring HIV Infection from Ophthalmic Medical Personnel

The risk of patients being infected by an ophthalmologist or ophthalmic medical personnel who has been infected with the HIV is considered extremely remote. Standard office practices, as discussed above, will minimize even the unlikely risk of contamination of patients. Surgical patients are protected by the routine use of barriers (e.g., gloves). Certainly, an instrument that punctures the skin of an ophthalmologist or the surgical assistant must be removed from the operating field and sterilized. The surgeon or assistant must reglove after all bleeding has stopped and any residual blood has been removed.

The CDC Guideline for Infection Control in Healthcare Personnel also provides advice about management of patient contact and other situations when health care personnel have HIV and other illnesses which could be transmitted to patients.[19]

II. Procedures for Protection for the Staff

Protection of the ophthalmic medical personnel involves preventive measures to avoid infection with ocular surface contaminants (such as adenovirus or herpes simplex virus), as well as bloodborne pathogens (such as HIV, HBV and HCV).

Bloodborne pathogen precautions further reduce the unlikely risk of contamination of the ophthalmic medical personnel and patient, alike. Employers under OSHA's rule with health care workers who are exposed to bloodborne pathogens are required to establish a program that informs employees and employers of the risks of occupational exposure to bloodborne pathogens and how to reduce those risks.[3]

Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's bloodborne pathogen precautions; but exposure to human tears does require good office hygiene practices such as handwashing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.

As the prevalence of HIV infection continues to increase throughout the United States, it is inevitable that patients carrying HIV will be more commonly encountered in eye examining rooms and in surgery. Some of these patients will be known to be infected with the HIV, but in many, it will be unrecognized. All health care personnel engaged in delivering ophthalmic care to such patients might, in the course of their normal duties, be exposed to the blood of individuals who may be shedding the virus. Although the risk of infection in these circumstances appears to be extremely remote, precautions by health care employers and employees are justified as recommended by the OSHA and the CDC.

The following recommendations for hygienic procedures to be used in the delivery of eye care to patients are effective ways to minimize this risk as well as the risks of contracting or transmitting other much more common infectious diseases encountered in patients. Because it is impractical to identify all patients who may be carrying these infectious agents, these recommendations should be the routine for all patient encounters.

General Precautions Against Infection – Office

A. Handwashing.

The hands should be washed with soap and water and thoroughly dried on a fresh or disposable towel between each eye examination. Fingernails should be kept short and clean. The hands and fingers should be inspected frequently for cuts, abrasions, and breaks in the skin or paronychia.

B. Gloves.

The CDC suggests in its recommendations for the prevention of HIV transmission in health care setting, released in 1987[7], and updated in 1988[8], that:

> "All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with the blood or blood-contaminated fluids of any patient is anticipated. Gloves should be worn for touching blood and blood-contaminated fluids, for handling items or surfaces soiled with such fluids and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other bodily fluids. Hands should be washed immediately after gloves are removed.
>
> Health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
>
> Pregnant health care workers are not known to be a greater risk of contracting HIV infection than health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission."

In accordance with these recommendations, disposable gloves should be readily available for all ophthalmic medical personnel and they should be instructed regarding the rationale for wearing gloves and their appropriate usage. It should be noted particularly that gloves:

- Are not a substitute for handwashing, and
- Are for single use only, and should be discarded after each patient encounter.

C. Gowns and Masks.

Gowns and masks are unnecessary in the normal ophthalmic office setting.

D. Protective eye wear.

In situations when splashing with blood or blood-contaminated fluids may be anticipated, protective eyewear is indicated.

E. Handling of tissue.

In the course of assisting in the examination of eye patients, ophthalmic medical personnel may be required to handle the eyelids and surrounding facial skin and thus, may come in contact with tears and the conjunctival membrane. To minimize direct contact with these tissues, particularly if the patient has a known or suspected eye infection, ophthalmic medical personnel should be instructed in the use of gloves or in "no-touch" techniques involving the use of cotton-tipped applicators to stabilize the tissues whenever possible.

F. Hepatitis B vaccination.

Ophthalmic medical personnel who frequently come in contact with needles, blood or blood products are advised to receive hepatitis B vaccine to avoid infection with the virus.[3] OSHA regulations require that the employer make hepatitis B vaccine available to all employees who have occupational exposure.[4]

Procedures

A. Handling of sharp instruments.

The CDC has recommended that all health care workers adopt precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices[8]:

- During procedures
- When cleaning used instruments
- When disposing of used needles, and
- When handling sharp instruments after procedures

To prevent needlestick injuries, ophthalmic medical personnel should be instructed in the proper handling of needles, i.e., needles should not be recapped, or purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Health care workers should be instructed to place disposable syringes and needles, scalpel blades and other sharp items in puncture resistant containers following their use. Puncture resistant containers should be provided and should be located as close as practical to the area where needles and syringes are in use. Newer devices have engineering controls such as injury protections and needleless systems to minimize injuries.

OSHA's revised Occupational Exposure to Bloodborne Pathogens Standard now requires that the employers governed by this rule review annually and update to reflect changes in technology that could reduce exposure to bloodborne pathogens, and maintain a sharps injury log.[20] OSHA's Bloodborne Pathogens Standards applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials. However, workplaces with 10 or fewer employers are exempt from OSHA recordkeeping requirements, including a Sharps Injury Log.[21]

B. Fluorescein and Indocyanine green (ICG) angiography.

It is recommended that photographers and other health care workers who may come in contact with blood while performing fluorescein and ICG angiography wear gloves and adhere to the procedures as outlined in this section.

C. Contact lens fitting.

Ophthalmic medical personnel involved in the fitting of contact lenses should be instructed in the precautions outlined by the CDC for disinfection of lenses.[4]

D. Minor office surgical and diagnostic procedures.

During the performance of minor surgical and diagnostic procedures, particularly where contact with blood or blood-contaminated fluids may occur, gowns, disposable gloves and masks, and protective eyewear should be worn.

Surgery

Ophthalmic medical personnel assisting at eye surgery should be instructed to avoid the direct handling of needles and those parts of instruments that have come into contact with body tissues and fluids. Thus, needles should be manipulated with forceps or needle holders rather than by the gloved fingers, instruments should be held by the handle rather than by the tips, and the cleaning of instruments should be performed in such a way that accidental perforation of the gloves is avoided. If an instrument punctures a glove or the skin, it must be removed from the operating field and sterilized. These practices should be incorporated into standard operating room infection control procedures and should be monitored for compliance, as are other infection control procedures.

If an ophthalmic medical personnel does accidentally sustain a skin puncture, the following actions should be taken. The individual should temporarily discontinue participation in surgery (if possible) and cleanse the wound for five minutes with an antiseptic solution.

The wound should then be dressed with a bandage after rescrubbing. If there is no oozing or weeping of the wound, the person may reglove, and complete the surgery.

Under experimental conditions, it has been reported that oral polio vaccine virus was cultured from the laser plume after excimer laser ablation.[22] Another experimental study postulated that infectious virus particles could be aerosolized during excimer laser photoablation.[23] Another study using a model system did not find any transmission of virus by the excimer laser plume.[24] It seems prudent then to maintain the same procedures in excimer laser surgery procedures as practiced as in other surgical procedures, e.g., masks, gloves, sterilization of instruments, etc.

Management of Exposures

These recommendations are based on the U.S. Public Health Service Guidelines, published in 2001.[2] Occupational exposures are considered urgent medical concerns so that timely management can be administered.[2] Studies show that postexposure prophylaxis should be initiated as soon as possible, because it is most effective within 24 to 36 hours after exposure. However, even after 24 to 36 hours, it can be considered, because it might still be effective.

If a person has been exposed to a source person already known to be seropositive for HIV or there is a strong likelihood that the source person is HIV infected, then postexposure prophylaxis (PEP) can be initiated as soon as possible, in consultation with physicians with expertise in antiretroviral therapy and HIV transmission. If the source person's HIV status is not known, the use of PEP can be decided on a case-by-case basis. All persons with occupational exposure to HIV should receive follow-up counseling, testing and medical evaluation. For HIV PEP, recommendations include a basic 4-week regimen of drugs, if tolerated, and an expanded regimen for exposures that pose an increased risk for transmission.[2,25]

If the source person is seronegative for HIV, then baseline testing or further follow-up of the exposed health care personnel is not necessary. Otherwise, health care personnel should be tested for HIV within hours of exposure. Serologic testing should be made available to all health care personnel who are concerned that they might have been infected.

For personnel exposed to HBV, it is recommended to initiate the hepatitis B vaccine series to an unvaccinated person, and provide PEP with hepatitis B immune globulin or hepatitis B vaccine in appropriate cases, preferably within 24 hours.[1]

For personnel exposed to HCV, the Public Health Service does not recommend immune globulin or antiviral agents as PEP.[2] However, there have been studies outside the United States that have utilized interferon early in the course of acute hepatitis C to prevent the establishment of chronic hepatitis C.[2,26] In case of percutaneous or mucosal exposure to blood, the CDC recommends that health care institutions have policies to follow-up for HCV infection, which could include testing of the source person for anti-HCV antibodies, and follow-up testing for anti-HCV antibodies of the affected personnel, if the source person is found positive for HCV.[2]

If there is exposure to blood, fluid containing visible blood, or other potentially infectious fluid (not including tears), then the status of the source person should be evaluated for HIV, HBV, and HCV infection as soon as possible.

It is recommended that health care organizations have systems in place for prompt reporting, evaluation, counseling, treatment and follow-up of occupational exposures to bloodborne pathogens.[2] Health care personnel should be educated to report occupational exposures immediately after they occur, because treatment can be most effective if administered as soon as possible after the exposure. Employers subject to OSHA regulations are required to establish exposure control plans that include post-exposure follow-up and to comply with incident reporting requirements.[4]

III. Procedures for protection of the ophthalmologist

Ophthalmologists might be at risk of acquiring HIV, HBV or HCV infection in their professional activities from two major sources: 1) the patient examination, and 2) the setting of surgical intervention.

<u>General Precautions Against Infection – Office</u>

The ophthalmologist personally should follow the same procedures designed to protect office staff and described in Section II. These include handwashing, wearing of gloves where appropriate and taking precautions to prevent injuries caused by needles, scalpels and other sharp instruments. Avoid touching one's own eyelids or contact lenses with the fingers without thorough hand washing.

In the normal ophthalmic office setting, gowns, masks and protective eyewear are usually unnecessary except in situations when splashing with blood or blood-contaminated fluids may be anticipated.

<u>Minor Office Surgical and Diagnostic Procedures</u>

The universal precautions should be observed when performing minor procedures and intravenous fluorescein angiography. In addition to gloves and masks, protective

eyewear should be used if there is a possibility of blood or body fluid splashing.

Surgery

Ophthalmologists are probably most at risk of exposure to HIV and other bloodborne pathogens while performing or assisting in surgery. The following procedures are recommended during surgical procedures:

- Adopt universal precautions for all patients
- Wear gloves when performing all injections
- Handle suture needles with needle holders only
- Develop techniques for safe handling and transfer of sharp instruments
- Follow guidelines given in Section II regarding surgery

IV. Responsibilities Towards Patients with Known or Suspected HIV Infection

Like all physicians, ophthalmologists have a moral and ethical responsibility for providing care to all patients, regardless of whether they are known to be infected with HIV, are known to be seropositive or fall within a "high-risk" group.

Ophthalmologists and ophthalmic medical personnel are at little risk of contracting HIV infection in the course of routine clinical practice. Risks may be further minimized when dealing with those known to be seropositive or suffering from clinical AIDS, but one should remain cognizant of the fact that many seropositive individuals have not been tested. Given the above scenario, bloodborne precautions are warranted for all appropriate patients.

Conclusion

The risk of contracting HIV infection in the ophthalmic healthcare setting is estimated to be extremely remote. Although HIV has been isolated from tears and other ocular fluids, the titer is extremely low and is considered by many authorities to be below an inoculating dose. To date, there is no evidence that the infection has been acquired from contact with tears. However, it must be remembered that these precautions will be effective against other more infectious agents than may be encountered in patients with HIV infection. These OSHA and CDC guidelines are intended to help protect the public and ophthalmic medical personnel, and minimize transmission of bloodborne pathogens and surface infectious agents.

Additional Resources:

Further information on the CDC guidelines can be obtained by viewing the CDC website for Division of Healthcare Promotion http://www.cdc.gov/ncidod/hip/.

Further details on the OSHA regulations including regulations governing HIV and HBV research laboratories and production facilities can be obtained by viewing the OSHA website (http://www.osha.gov/) or ordering publications online (http://www.osha-slc.gov/OshDoc/Additional.html)

Occupational Safety and Health Bloodborne Infectious Disease
www.cdc.gov/niosh/bbppg.html

State needle safety legistation: www.cdc.gov/niosh/ndl-law.html

Exposure management resources:

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
1-888-448-4911

Needlestick! www.needlestick.mednet.ucla.edu

Hepatitis hotline 1-888-443-7232

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP
1-800-893-0485

HIV/AIDS treatment information service
www.hivatis.org

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Approved by: Quality of Care Secretariat

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3.3 Fluorescein Angiography Frequently Asked Questions

Q: Can the FA Light Source generate other colors and wavelengths of light?
A: No, it is designed for 471 nanometer blue excitation exclusively.

Q: How long does the Xenon bulb last?
A: The bulb is a special order and extensive testing data does not exist. However, a guideline is that the intensity may reduce to one half the original value after 50 hours of use, and then continue to reduce slowly after that. Some users have been performing successful FA imaging up to 200 hours of lamp time.

Q: Can the bulb be replaced in the field?
A: It is not designed for field replacement. Return the unit to the factory if the output is reduced or the lamp will not illuminate. Call Customer Service for assistance.

Q: How much does a replacement bulb cost?
A: It depends on the circumstances and what else is out of specification at the time of service. You will be quoted the costs for repair of your FA Light Box before any work is begun.

Q: Can I get a replacement barrier filter if mine is lost or broken?
A: Yes, contact Customer Service for a quotation.

Q: Can the FA Light Source be returned for service without returning the whole RetCam II?
A: Yes, the FA Light Source is a module that is removable by a person with the skill level of a nominal biomedical technician. Be sure to package it as a sensitive medical instrument with at least 3" of padding on all sides in a sturdy box, sealed well, shipped insured for USD $20,000. NOTE: Clarity can send appropriate packaging material to you if needed.

Q: My FA Light Source turns itself off. It comes back on in a few minutes, or if I turn the power off and back on. What's wrong?
A: The temperature sensing circuit is protecting the Xenon lamp. It may not be working properly. The FA Light Source may need repair and it may be a warranty issue regardless of the age of the unit. Contact Customer Service for advice on how to clear the condition or to schedule service.

3.4 **Servicing the Interior of the Cart**

WARNING: Removing the back panel should be done by qualified technical personnel only. Maintenance personnel should be familiar with the usual precautions regarding the service of electronic and electrical equipment. In addition, the RetCam II contains an uninterruptible power supply (UPS) that contains batteries. The UPS will NOT be disconnected when the main power plug is removed from the wall. Precautions must be taken to ensure that the UPS is not energized before performing maintenance inside the cart.

The computer, Light Box, Fluorescein light source (option) and image printer (option) are modules that can be removed from the back of the cart if necessary. Make note of the cable connections before removing a module.

Contact Customer Service for help troubleshooting problems to the module level before removing any modules. Many problems can be traced with the help of substitute harnesses and voltage measurements made in the cart without removing any modules.

Service to the UPS requires removal of the image printer (if present), and disassembly of the base cover. Contact Customer Service for detailed instructions for removal and replacement of the UPS if service to the UPS is required.

WARNING: When doing this level of service, Electrical Safety Retesting of the system is required to maintain compliance with IEC requirements. Contact Customer Service before beginning.

4.0
Specifications

Hardware

Physical

24”(610 mm) wide x 27.4”(697 mm) deep x 47”(1193 mm) high, display folded down
61”(1546 mm) high, with display up
Dual 5” front locking casters.
Approximately 235 lbs. (107 Kg) basic unit
Low center of gravity.

Electrical

Power consumption: 750 watts maximum with all options.
North American version: 115 VAC, 60 Hz
Detachable hospital grade power cord
International version: 230 VAC, 50 Hz

Cart Features

Internal Medical Isolation Transformer satisfies IEC 60601-1
Internal Uninterruptible Power Supply.
Membrane control panel with status LED’s.
Waterproof keyboard and trackball.
LCD flat panel display with $\leq$25 mS response.
Custom display arm for angle and height adjustment.
Integrated cooling ducts with quiet, forced-air cooling and filtered inlets.
Dual 5” front locking casters
6” rear wheels

Storage drawer

Tri-function footswitch
Camera cable hanger
Dust cover
Report Printer (Option)

Custom Light Source

Adjustable intensity iris
Automatic black and white balance functions
S-Video (NTSC) output
Lens focus motor connector
Custom fiber optic with interlock
Automatic fan speed controller
Easy-access bulb replacement

Handheld Imager

3-chip RGB CCD
Full 24-bit color
Quick-change front lens assemblies, 5 styles

Embedded Computer
Intel® Processor
1GB memory
120 GB storage
Dual 9.4 GB Internal DVD-RAM Drives
4-port USB Hub
Audio
10/100 Ethernet Adapter
Graphics Accelerator

Fluorescein Angiography light source (option)
Continuous arc Xenon light source
Narrow-line blue excitation filter (471 nm)
Iris intensity control
Fiber optic safety interlock
Green emission (blocking) filter for handheld imager (510 nm)

Dye-Sublimation Color Image Printer (option)
Mitsubishi medical grade printer
Easy access drawer for paper replacement
Single or dual printouts with or without annotation

Software

MS Windows XP Embedded operating system
Proprietary image acquisition, storage and processing
Live color image display
Integrated patient database.
Still and 20-second video capture modes
Review functions
Compare functions
Data export as XML, CSV or TXT with automatic patient organization
Image export as bitmap, jpeg, or png
Image annotation
Fluorescein Angiography mode
Monochrome image storage (green channel)
Timed auto-save
Time-stamped images

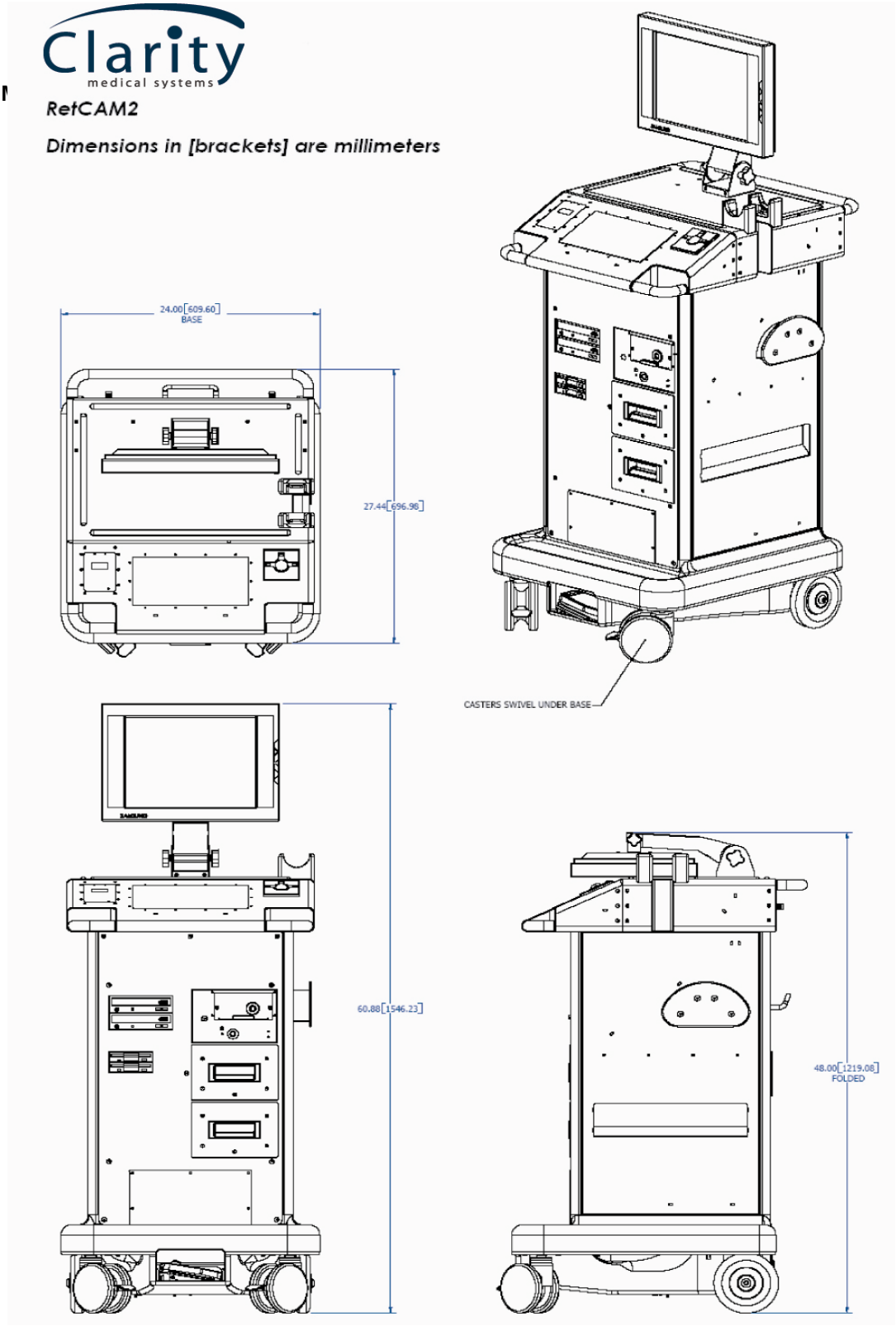
Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures and humidity, upright, on a level surface, with the brakes applied to the front casters

and the dust cover off for proper ventilation.

Condition	Operating	Storage and Transport
Temperature	59º to 95º F (15º to 35º C)	-4º to 122º F (-20º to 50º C)
Relative Humidity	10% to 93% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Note: Specifications subject to change without notice.


Clarity
medical systems
RetCAM2
Dimensions in [brackets] are millimeters
24.00[609.60]
BASE
27.44[696.98]
CASTERS SWIVEL UNDER BASE
60.88[1546.23]
48.00[1219.08]
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Section 5 RetCam II Troubleshooting Guide	
Issue:	**Troubleshooting recommendations:**
No power to Ret Cam II system.	If the green light on the membrane control panel is not flashing then verify the power switch on the back of the system is turned on and the power cord is plugged into the appropriate outlet. If the system has not been plugged into the wall for at least 4 hours before the intended use, plug the system in to let the UPS battery charge then press the power button on the membrane control panel. If only the light from the handpiece is on when the power button is pressed it is possible the UPS has failed and will need to be replaced. Contact customer service at Clarity Medical Systems. Verify power cord connection. Verify power source is correct voltage for system and is functioning correctly. Verify the main power switch in the back of the RetCam system turned on.
No Display	The display will be dark initially while the program is loading. If the display is still dark after a few minutes then verify the monitor is turned on. Verify monitor power indicator light is on. Verify monitor cable and power cord are connected properly. Verify computer is on. Verify monitor functionality; • Connect monitor to alternate system. • Connect alternate monitor to system. Verify system Display settings are correct.

No Operating System	Restart the system. Verify system BIOS is loading and displaying on monitor. Verify if any error messages are displaying and obtain details. If there is an error message when the system is turned on that is not recoverable, record the error then reboot the system by pressing and holding the power button on the membrane control panel for 6 seconds. Wait 6 seconds before turning the system back on.
No RetCam II program	Restart the system. Verify RetCam splash screen displays. Verify error messages displayed. Obtain details. Verify if system is connected to network. If so, disconnect from network and restart the system. Verify RetCam program is present under. C:\Program Files\Massie Research Labs.
No Camera Image	Verify connections are properly connected. Verify the hand-piece camera cable is connected to the light-box. Verify the camera cable is inserted and threaded on. Verify there is an S-video connection in the front of the light-box. Can an image be seen when an auxiliary monitor is connected to the S-video connection?
Unable to Save Image	Verify destination location of file to be saved, (local, DVD, USB, network, etc.) Verify sufficient space at destination location. Verify any error messages displayed while saving. Obtain details. .

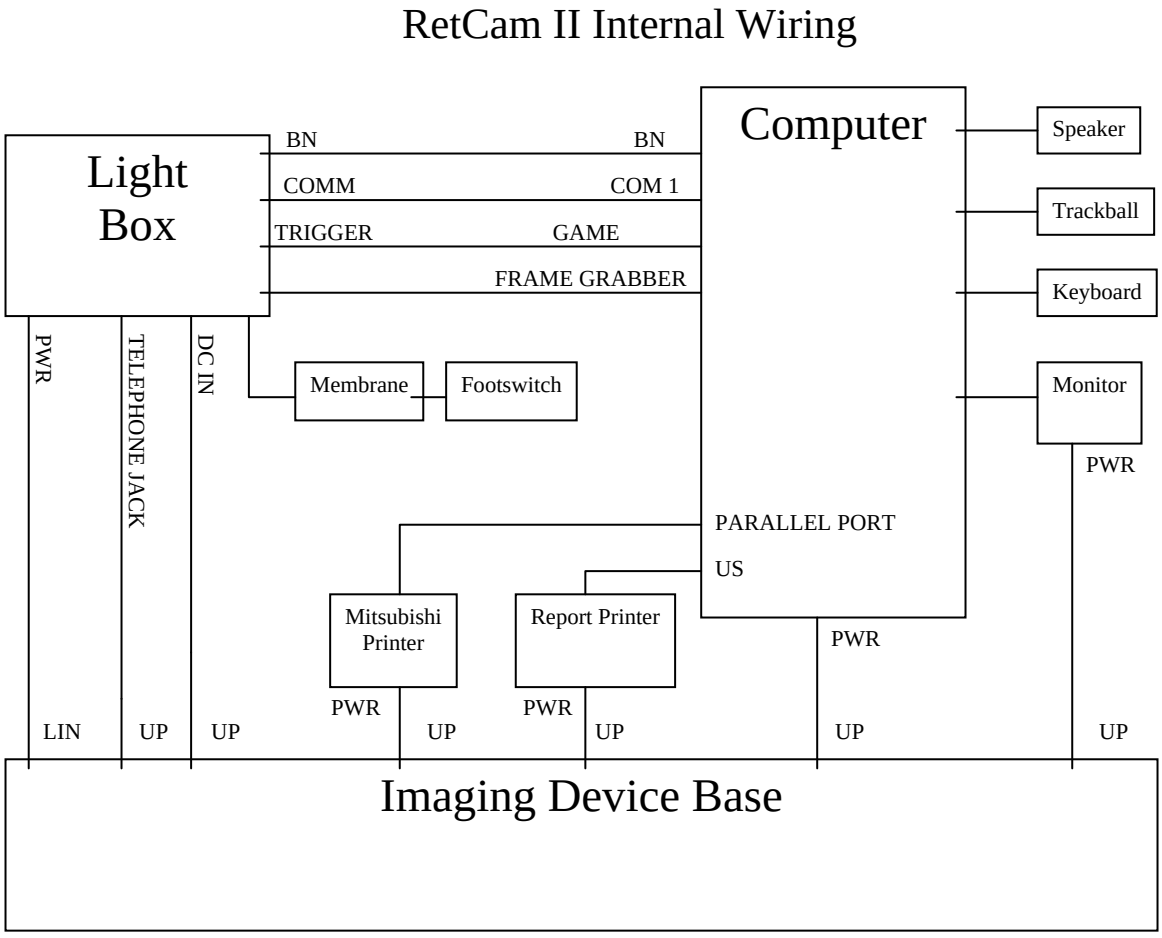
Unable to Transfer an Image	Verify file transfer destination location. Verify drive/device is resident in RetCam program. Verify drive/device is recognized in File Explorer. If failing network file transfer, • Verify you have successful connectivity to network Share directory. • Verify you are successfully logged on. • Verify network share file parameters. .
Unable to Print Report or Image file	Verify printer type, (image or report printer). Verify printer power indicator lights are on. Verify printer cable connections are properly connected. Verify if any printer error codes displaying. Verify printer media is properly installed. Verify correct printer driver is installed. .
No Light from hand-piece	Verify the fiber optic from the handpiece is inserted in the fiber optic port of the lightbox and the lamp button on the membrane control panel is turned on. Leave the lamp off for 10 minutes to allow the lamp to cool down and then turn it back on. If after these measures are taken the lamp does not turn on, then replace the illumination bulb. See the section in the User or Service manual for Changing the illumination bulb. .
Light intensity does not increase or decrease	Press the light intensity button on first the membrane control panel and then the light intensity peddle on the footswitch to change the intensity of light coming out of the handpiece. If the intensity does not change with either then contact customer service. If it is determined the lightbox needs to be replaced then upon receiving the part follow procedure 30-000001 for Lightbox Replacement.

Live image problem	If the color of the live image is not balanced perform the Automatic White Balance procedure in the User or Service manuals If there are color 'streaks' in the live image the handpiece will need to be sent in for service. Contact customer service at Clarity Medical Systems. .
Image does not focus	Verify the focus cable is connected to the light-box. When the focus button is pressed verify the motor within the handpiece can be heard turning. o If the motor cannot be heard, then contact Clarity Medical Systems. o If the motor can be heard, see the following steps; Check for cleanliness of the lenspiece. See procedure 800138 on Hand-piece Focus For further assistance please contact Clarity - Service Dept. @ (800) 215-6005.
Image capture is not working	If a live image can be taken using the software, verify that an image can also be captured using the membrane control panel button. If an image can be taken using the the membrane panel button then take an image using the snap button on the footswitch. If the image can be taken using the snap button on the footswitch, i but not the membrane panel, the membrane panel will need to be replaced. See procedure 800096 for Membrane Control Panel Replacement.

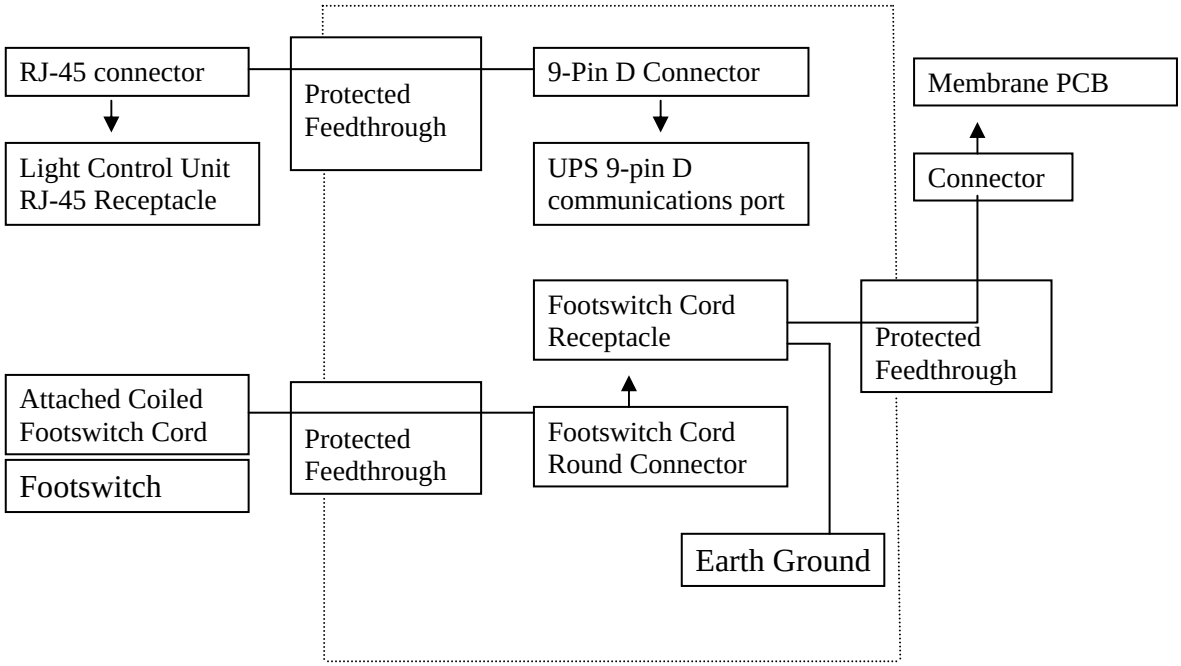
Button on the membrane control panel is not working	If it is determined the membrane control panel needs to be replaced then upon receiving the part follow procedure 800096 for Membrane Control Panel Replacement. .
No numbers displayed on membrane panel for light intensity	If the system is turned on and the RetCam program is displayed on the monitor but no numbers appear on the membrane control panel for light intensity then press the intensity button to turn the lamp on.
USB stick is not recognized	Since the operating system of the RetCam II is embedded not all USB sticks will be recognized. If the USB stick is not recognized in the Utilities screen then use the SanDisk USB stick provided by the company.
Keyboard is not working	If repairs to the computer have been performed recently then verify the keyboard cable is inserted into the keyboard connection at the computer. If it is determined the keyboard needs to be replaced then Contact customer service and upon receiving the keyboard follow procedure 800095 for Keyboard Removal/Replacement.
The UPS beeps when the system is unplugged	This is the normal part of the operation. See the section in the User Manual covering System Description for the Uninterruptible Power Supply (UPS). The UPS supplied power is intended only for relocation of the system and live imaging should not be done when the system is unplugged.
The system turns off when it is unplugged and moved	This can happen when the UPS battery is in a low charge condition. The normal time a system can be unplugged from the power source with the program running will range from 10 to 20 minutes on a fully charged battery. The RetCam II must be plugged in for live imagining. It is best to leave the RetCam II plugged in with the green light on the membrane control panel flashing when not in use.

The trackball is dirty	With the system turned off and unplugged, use an alcohol wipe to clean the trackball. If the trackball does not move smoothly see procedure 800134 for Trackball Cleaning.
The trackball does not work	If repairs to the computer have been performed recently then verify the trackball cable is inserted into the trackball connection at the computer. If the trackball needs to be replaced then refer to procedure 800111 for Trackball Replacement.
No light from the FA	Verify the fiber optic from the handpiece is fully inserted in the fiber port of the FA. If no blue light can be seen while the light switch on the front of the FA is turned on then the module will need to be returned to the factory for service. To reinstall the FA after service refer to procedure 800093 concerning the FA.
Blue FA light stays on when system is turned off	To turn off the FA light press the light switch on the front of the FA.
There is no network connection	Contact your Information Technology (IT) department.
The front castors on the system need to be replaced	See procedure 800099 on Front Castor Replacement.

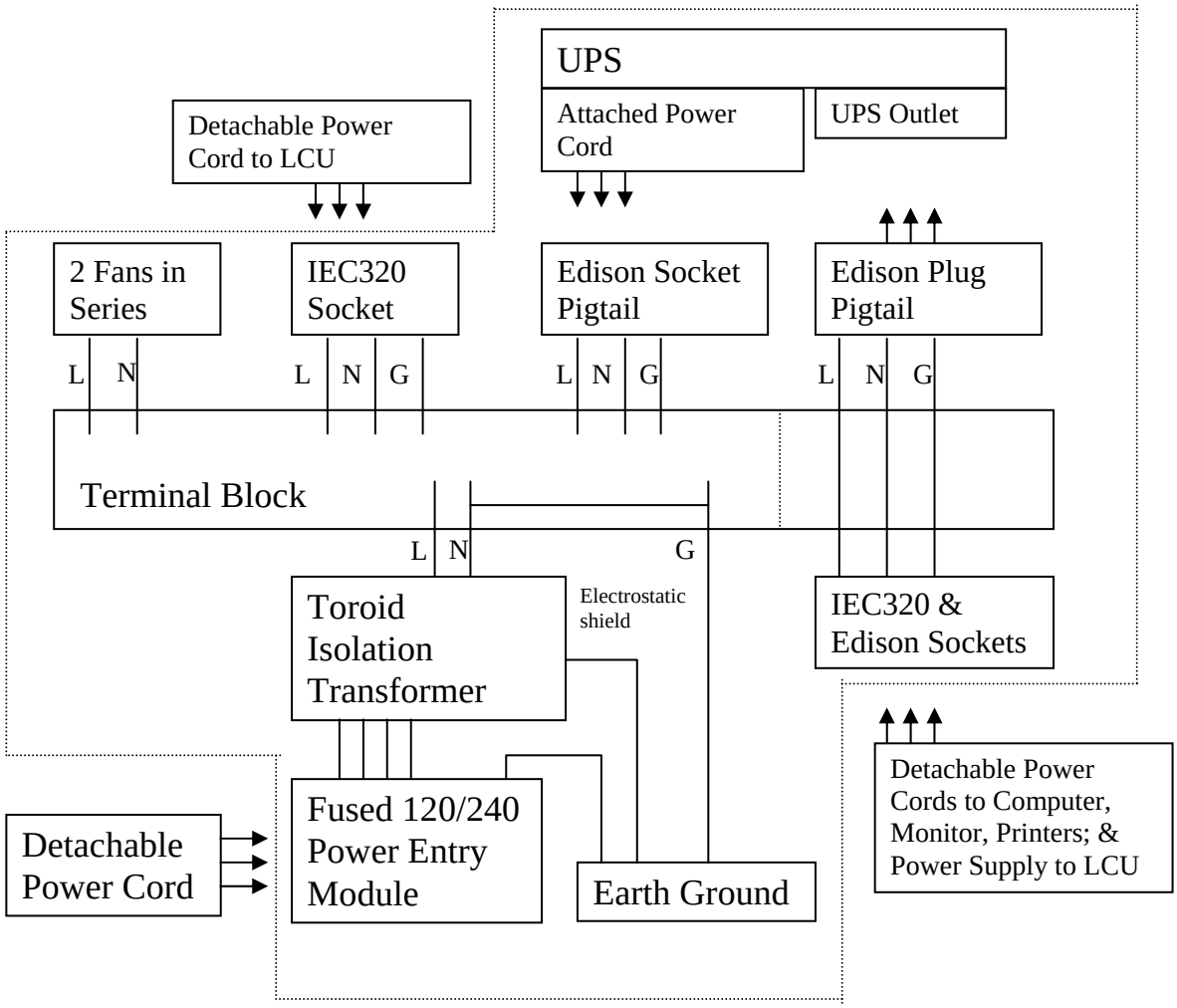
6.0
Block Diagrams



RetCam II
Base Low Voltage Wiring



RetCam II Base AC Wiring



7.0
Replacement Parts

Spare parts and supplies can be ordered by calling or faxing the part description and number to Customer Service.

Consumables:

Illumination Bulb (halogen)	02-04-501
DVD-RAM Disc	03-12-028
USB STICK	03-12-025
Image Printer Paper & Ribbon	03-12-004(Model No. CP770DW)
Image Printer Paper & Ribbon	03-12-005(Model No. CP900DW)
10-amp 125 volt fuses	02-04-037
5-amp 250 volt fuses (slo-blo)	02-04-038

Components:

Flat Panel Display	Contact Customer Service
Computer Assembly	03-00-016
UPS 620 C	04-04-020
Footswitch	12-00-065
Handpiece	01-00-201
Lightbox	13-00-000
Portrait Lens	01-00-017
FA Filter	09-00-015
FA install Kit (order with a new FA)	04-00-910
FA Lightbox	09-00-001
Image printer w/install kit	04-00-067

8.0
Technical Support

How to Get Support

The User Manual and Service Manual have been written to answer the majority of questions that arise with the product. Please consult these manuals before calling for service.

Clarity Medical Systems, Inc.'s (CMS) in-house technical staff is dedicated to helping our users with any specific problems and questions you may have with the RetCam II. Please have your serial number ready and include the serial number on all correspondence. The serial number is located on a sticker affixed to the base of the cart at the back just above the power cord connection.

Please be as specific and give as much information as possible. If you encounter a system malfunction of any kind, please record the exact steps taken leading to the failure, so that our staff can replicate the problem.

Off-shore customers, please contact your distributor.

In the US, please call: **Telephone Support:** (800) 215-6005
FAX Support: (925) 251-0078

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

or write to: Clarity Medical Systems, Inc.
5775 West Las Positas Blvd.
Pleasanton, CA 94588
USA

or email to: service@retcam.com

Our technical support staff will respond to your questions as soon as a staff member is available. In most cases, you should receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur engineering charges. Please ask for an hourly quotation before incurring charges.

Returning Parts for Repair

If a part or component is defective or damaged and is to be returned to Clarity Medical Systems for repair or replacement a Return Materials Authorization Number (RMA #) must be issued by CMS. The RMA number must be noted on the return shipping documents so that the disposition of the part is known when it is received at CMS offices.

Should your CMS product prove defective during the period covered by this warranty, please call, FAX or write to CMS at the numbers and address listed above for an RMA number. Each separate part must be securely packaged and returned to CMS in its original shipping container or an equivalent. Please clearly mark the outside of each returned package with the RMA number.

CMS will, at its option, repair or replace any defective or damaged part or component. Determination regarding whether service and repairs are completed at the customer site or the defective or damaged part(s) are returned to

CMS‘s facilities for repair shall be made by CMS on a case by case basis. Costs incurred to complete service or repair, including parts, labor, travel and shipping, not covered by warranty will be billed to the customer upon successful completion of the service or repair.

9.0
License Agreements

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This Software and accompanying written materials are provided with Restricted Rights. Use, duplication, or disclosure by the U.S. Government is subject to restrictions applicable to commercial computer software (under FAR 52.227--19 and DFARS 25.227-7013). Contractor/manufacturer is Clarity Medical Systems, Inc., 5775 West Las Positas Blvd, Pleasanton, CA 94588.

This Agreement is governed in and by the laws of the State of California, U.S.A. This statement gives you specific legal rights; you may have others which vary from state to state and from country to country. Clarity Medical Systems, Inc. reserves all rights not specifically granted in this statement.

Any attempt to decompile, reverse engineer or otherwise copy this software shall be considered a breach of this agreement.

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- **Limitations on Reverse Engineering, Decompilation, and Disassembly.** You may not reverse engineer, decompile, or disassemble the SOFTWARE, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.
- **SOFTWARE TRANSFER ALLOWED BUT WITH RESTRICTIONS.** You may permanently transfer rights under this EULA only as part of a permanent sale or transfer of the DEVICE, and only if the recipient agrees to this EULA. If the SOFTWARE is an upgrade, any transfer must also include all prior versions of the SOFTWARE.
- **EXPORT RESTRICTIONS.** You acknowledge that SOFTWARE is subject to U.S. export jurisdiction. You agree to comply with all applicable international and national laws that apply to the SOFTWARE, including the U.S. Export Administration Regulations, as well as end-use and destination restrictions issued by U.S. and other governments. For additional information see http://www.microsoft.com/exporting/.

10
Appendix

Appendix Table

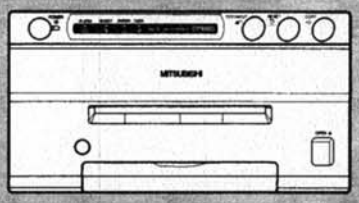
Appendix number	Procedure number	Revision	Document Name
1	Vendor	N/A	Mitsubishi Digital Color Printer CP900DW
2	800093	B	RetCam II Adding an Optional FA Light Source
3	800096	B	RetCam II Membrane Control Panel Replacement
4	800099	B	RetCam II Front Castor Replacement Procedure
5	800111	A	RetCam II Trackball Replacement Procedure
6	800134	A	RetCam II Trackball Cleaning
7	800136	A	RetCam II Replacing the Computer
8	30-000001	A	RetCam II Lightbox Replacement
9	N/A	N/A	Fuse Replacement
10	N/A	N/A	Changing the illumination bulb
11	800095	B	Keyboard Replacement
12	800138	A	RetCam Handpiece Focus

MITSUBISHI

DIGITAL COLOR PRINTER
MODEL

CP900DW

OPERATION MANUAL



THIS OPERATION MANUAL IS IMPORTANT TO YOU.
PLEASE READ IT BEFORE USING YOUR DIGITAL COLOR PRINTER.

CE

DIGITAL COLOR PRINTER

This digital color printer complies with the requirements of the EC Directive 89/336/EEC, 73/23/EEC, 93/42/EEC and 93/68/EEC.
The electro-magnetic susceptibility has been chosen at a level that gains proper operation in residential areas, on business and light industrial premises and on small-scale enterprises, inside as well as outside of the buildings. All places of operation are characterised by their connection to the public low voltage power supply system.

INFORMATION

This Class A digital apparatus complies with Canadian ICES-003.
Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1 AND CAN/CSA C22.2 NO. 60601.1.
57RF

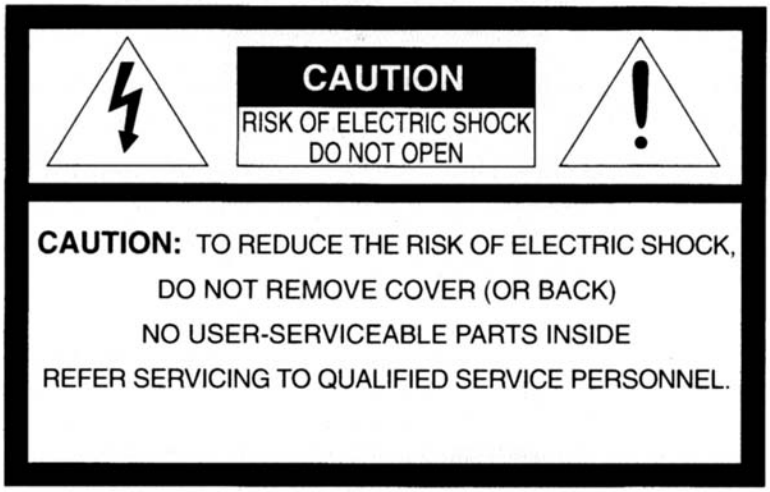
According to Clause 5 in UL 2601-1 sec 6.8.1, this unit is classified by the following;

- The type of protection against electric shock:
  EQUIPMENT energized from an external electrical power source:
  CLASS I EQUIPMENT
- The degree of protection against harmful ingress of water:
  Ordinary EQUIPMENT (enclosed EQUIPMENT without protection against ingress of water)
- The degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:
  EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
- The mode of operation:
  CONTINUOUS OPERATION

WARNING :
TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS APPLIANCE TO RAIN OR MOISTURE.

This product is to be employed with medical equipment, just for reference purpose, not for medical diagnostic purpose.

When you dispose of the unit or accessories, you must obey the law in the relative area or country and the regulation of the medical facility.


CAUTION
RISK OF ELECTRIC SHOCK
DO NOT OPEN
CAUTION: TO REDUCE THE RISK OF ELECTRIC SHOCK,
DO NOT REMOVE COVER (OR BACK)
NO USER-SERVICEABLE PARTS INSIDE
REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

The lightning flash with arrowhead symbol, within an equilateral triangle, is intended to alert the user to the presence of uninsulated "dangerous voltage" within the product's enclosure that may be of sufficient magnitude to constitute the risk of electric shock.

The exclamation point within an equilateral triangle is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the appliance.

NOTE:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his or her own expense.

WARNING:

Use the included AC power cord so as not to interfere with radio and television reception. If you use other cables, it may cause interference with radio and television reception.

SAFETY PRECAUTIONS

In the interest of safety, please observe the following precautions:

POWER REQUIREMENT

This product is designed for operation on 120V AC or 220-240V AC 50/60Hz. Never connect to any outlet or power supply having a different voltage or frequency.

WARNING: THIS APPARATUS MUST BE GROUNDED.

AVERTISSEMENT: CET APPAREIL DOIT ETRE MIS A LA TERRE.

PROTECTIVE MEASURES

IF ABNORMALITIES ARISE, ...

If the printer emits smoke or abnormal sounds, immediately unplug the power cord from the printer or power outlet. Continued use may be dangerous. Contact your dealer about having the printer checked and serviced.

NEVER INSERT ANY OBJECT INTO THE UNIT

Nothing other than supplies for this printer should ever be inserted into the printer. Other items can cause a safety hazard and extensive damage to the mechanism and electronics.

DO NOT SET HEAVY OBJECTS ON TOP OF THE UNIT

Heavy objects can damage the unit and/or cause misoperation.

AVOID DAMAGING THE POWER CORD

Do not set anything heavy on the power cord nor allow it to become pinched, or cut. If the power cord becomes damaged, replace it immediately to avoid shock hazard or electrical fire.
When the power cord is replaced, use the same type as originally supplied, it is designed to reduce interference to radio & TV reception.
When unplugging the power cord, hold the plug, and remove it carefully.

KEEP THE UNIT DRY - DO NOT PLACE WATER OR OTHER LIQUID CONTAINERS ON TOP OF THE UNIT

Liquids which get into the unit can cause serious damage to the unit and potential shock or fire danger. If liquid is spilled into or seeps into the unit, unplug the Power Cord immediately and seek service as soon as possible to avoid additional or possible damage due to corrosion.
"In the interest of safety, avoid handling of liquids near the unit."

DO NOT REMOVE THE CABINET. THERE ARE NO USER SERVICEABLE PARTS INSIDE AND YOU WILL EXPOSE YOURSELF TO HAZARDOUS VOLTAGES AND/OR YOU MAY CAUSE DAMAGE TO THE UNIT.

Touching internal parts is dangerous, and may cause a malfunction. Contact your dealer to carry out internal checks and adjustments. Disconnect the power cord before opening the cover to clear a paper jam, etc.

UNPLUG THE POWER CORD DURING A LONG ABSENCE OR DURING AN ELECTRICAL STORM

Turn off the Main Power switch and unplug the power cord during a long absence or during an electrical storm.

WHEN TRANSPORTING THE UNIT

When transporting the unit, remove the sheet cartridge and paper. Make sure to slide the printing mechanism lock switch to the lock position.

BE CAREFUL AROUND PRINT PAPER EXIT SLOT

Do not insert your fingers or any object into the paper slot during printing.
Do not touch the cutter blade inside the paper exit slot, it can cause injury.

DO NOT TOUCH THE THERMAL HEAD

It becomes hot during printing and may remain hot for a time, causing injury. Oils, salts and moisture from your hands will contaminate the head and may spoil the prints.

BE CAREFUL WITH THE PRINTING MECHANISM

Do not move the printer while the printing mechanism is open. This may cause injury.
Be careful not to catch your fingers in the printing mechanism when sliding the mechanism back into the normal closed position.

CONNECTING CABLES

Use the power cord supplied with the printer.

INSTALLATION LOCATIONS

MAINTAIN GOOD VENTILATION

Ventilation slots and holes are provided on the rear, sides and bottom of this unit. Place the unit on a hard and level surface and locate at least 4 inches (10 cm) from walls to insure proper ventilation. When installing the unit in a system rack, leave space between the unit and the back of the rack.

UNSUITABLE LOCATIONS

Avoid installing the printer in unstable locations with high vibration or in hot-springs areas where hydrogen sulfide and acidic ions are likely to be generated.

PLACES WITH HIGH HUMIDITY AND DUST

Do not place the unit in locations with high humidity and dust, as this can cause extensive damage. Avoid places where unit is likely to be exposed to oily fumes and vapours.

PLACES LIKELY TO BE EXTREMELY HOT

Places exposed to direct sunlight, or near heating appliances can attain extremely high temperatures which may deform the cabinet, or cause other damage.

PLACE THE UNIT ON A HORIZONTAL SURFACE

The operation of the unit is likely to be affected if it is tilted, inclined or in unstable places.

PROTECT AGAINST DEW FORMATION

When the unit is moved from a cold area into a warm area, moisture can condense inside the unit and prevent operation. Allow the temperature to stabilize before use.

OPERATING AMBIENT TEMPERATURE RANGE

The operating temperature range is 41°F - 104°F (5°C to 40°C) and humidity of 20 - 80%. When using the unit in a system rack, make sure that the temperature inside the rack does not exceed this range.

FOR LONG OPERATING LIFE

UNSUITABLE MATERIALS FOR THE PRINTER

Paint coat flaking and plastic deformation are likely to occur if the unit is wiped with chemical dusters, benzine, thinner or any other solvent, if rubber or PVC items are left in contact with the unit for a extended period, or if the unit is sprayed with insecticide.

CARE OF THE CABINET

Unplug and clean with a soft cloth slightly moistened with a mild soap and water solution. Allow to dry completely before operating. Never use petroleum based solutions or abrasive cleaners.

HEAD ABRASION

The thermal printhead, like a video head, wears out. When it is worn, it becomes hard to print out fine details of the picture. If it occurs, consult your dealer about having the head replaced.

SAFETY PRECAUTIONS

CONNECTING DEVICES

Read thoroughly the Safety Notices, Cautions and "Operating Precautions" of the instruction booklets for the other devices connected with the unit.

CAUTION ON RELOCATING

When transporting the unit, make sure it is not likely to be subjected to impacts. This can be a primary cause for damage. Before moving the unit, make sure to disconnect the power cord from the power outlet, and the cables from the connected devices.

SAFETY CHECKS

Periods: According to the recommendations of the manufacturer of medical device.

Scope: a) Visual inspection
Housing, leads, controls, displays, labels/ markings, accessories, operation manual.

b) Functionality test
Testing of functions (according to operation manual) as well as compatibility and usability of device and accessories.

c) Electrical test
Testing of electrical safety of the system according to EN60601-1.

High humidity or dust
Avoid locations with high humidity and dust in order to avoid malfunction.
Also avoid locations subject to corrosive gasses and smoke.

Heat
Direct sunlight, heaters or other heat sources may deform the housing and subsequently cause malfunctioning.

TECHNICAL DESCRIPTION

The supplier will make available on request such circuit diagrams, component part lists, descriptions, calibration instructions or other information which will assist the USER's appropriately qualified technical personnel to repair those parts of the EQUIPMENT which are classified by the manufacturer as repairable.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
- use of the accessory in the PATIENT VICINITY
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate EN60601-1 and/or EN60601-1-1 harmonized national standard.

The transportation and storage environmental conditions are:
Temperature : -20°C - +60°C (-4°F - +140°F)
Humidity : 90%RH or less at 40°C(104°F)
Atmospheric pressure : 500 hPa - 1060 hPa

OTHER CAUTIONS

Dust or other foreign matter adhering to the print paper or the sheet cartridge, or deformation resulting from exposure to extremely low or high temperatures could cause loss of color, uneven color or lines, or wrinkles in the print images.

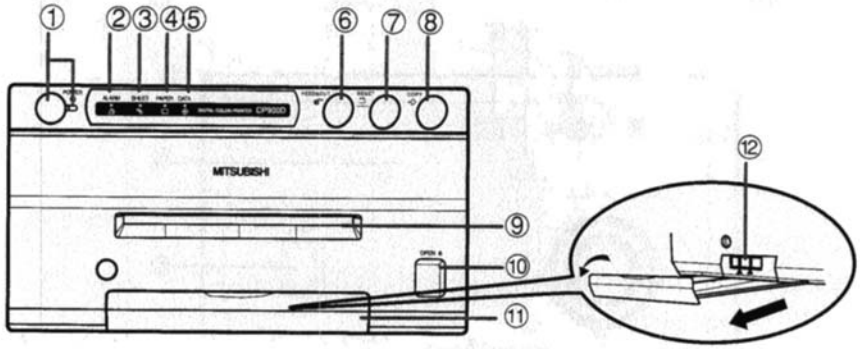
NOTE:
MEMORIZED IMAGES ARE STORED IN VOLATILE MEMORY AND MAY BE LOST IN THE EVENT OF POWER FLUCTUATION OR MALFUNCTION.

As for paper sheet set, refer to page 21, "Options".

WARNING :
Use the USB cable according to the recommendations as below, in order to comply with EN60601-1-2.
The USB cable with appropriate plug should be 2m long or shorter, comply with USB 2.0 standard High speed requirements and USB IF (USB Implementers Forum) approved.

Information:
This equipment complies with EN55011, class B, group 1.

FRONT PANEL



① POWER BUTTON(INDICATOR)
Press to turn on power. Press again to turn off power. When the power is turned on, the indicator illuminates.

② ALARM INDICATOR
When this unit is overheated, this lamp flashes. When other errors occur, the LED is steady. See page 17.

③ SHEET ERROR INDICATOR
When an error concerning ink sheet occurs, this indicator lights up or blinks.

④ PAPER ERROR INDICATOR
When an error concerning print paper occurs, this indicator lights up or blinks.

⑤ DATA INDICATOR
Indicator blinks during data transfer. It is steady while printing and during feed&cut function.

⑥ FEED&CUT BUTTON
Pressing this button, the print paper is fed and cut. And the mechanism will be initialized.

⑦ RESET BUTTON
Reset the print count to 1 when this button and ⑥ FEED&CUT button are pressed together.

⑧ COPY BUTTON
When pressing this button, the memorized data will be printed.

⑨ PRINT OUTLET
The printed paper comes out here.
Do not put any objects in front of the outlet.

⑩ OPEN BUTTON
Press to slide out the printing mechanism. Make sure to unlock ⑫PRINTING UNIT LOCK SWITCH. Reset the power if this button does not open the printing mechanism. Then try to press this button again.
Open the mechanism to load paper and ink cassette or to clear a paper jam.

⑪ TRAY
Hold the printed image that comes out of the print outlet. Press down and pull the knob to extend the tray. Make sure to fully extend the tray for proper use.

⑫ PRINTING MECHANISM LOCK SWITCH
Locks the printing mechanism.
Shift the switch to the left (LOCK side) to lock and to the right (UNLOCK side) to unlock.
This mechanism is locked when shipping. When transporting this unit, make sure to lock the mechanism.

BEFORE OPERATION

Before printing,
1. **Unlock the printing mechanism. (See below)**
2. **Install the print paper and ink cassette. (pages 11-15)**

PAPER SHEET SET

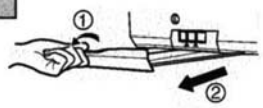
Make sure to use the following types of paper sheet and ink sheet set.

■ PAPER SHEET SET

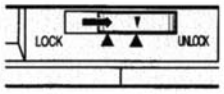
Product name	Ink sheet size	No. of prints	Usage
CK900S	S size	200	Colour print
CK900L	L size	130	Colour print
CK900S4P	S size	130	Surface-laminated colour print
CK900L4P	L size	90	Surface-laminated colour print
CK900S4P(HX)EU	S size	130	Surface-laminated colour print for ID photo
CK900L4P(HX)EU	L size	90	Surface-laminated colour print for ID photo

UNLOCK THE PRINTING MECHANISM

■RELEASING THE PRINTING MECHANISM LOCK



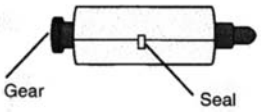
1 Press down and pull the knob to extend the paper tray.



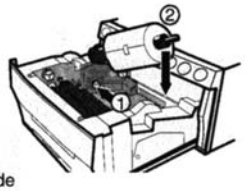
2 Shift the printing mechanism lock switch to the right (UNLOCK). (See page 8.)

INSTALLATION OF PRINT PAPER

Do not remove the seal on the print paper yet.



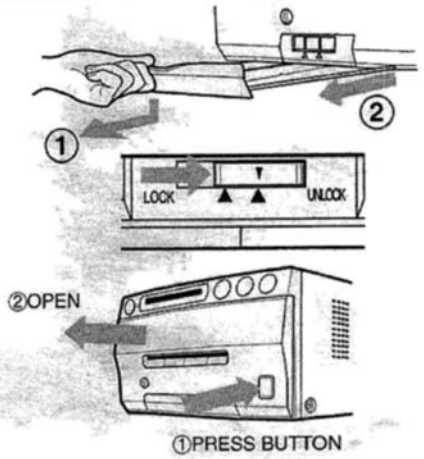
1 Insert the print paper roller with gear on the left.
Press the folder ① as shown right, and set the print paper roller.



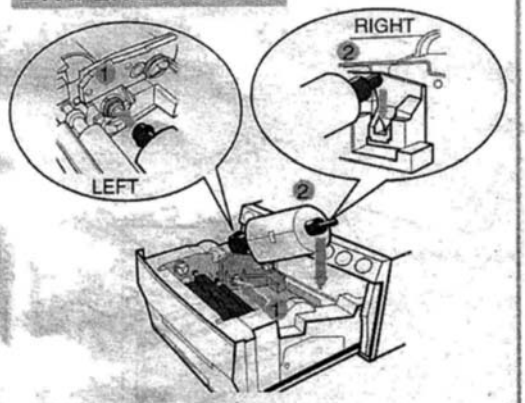
Front side

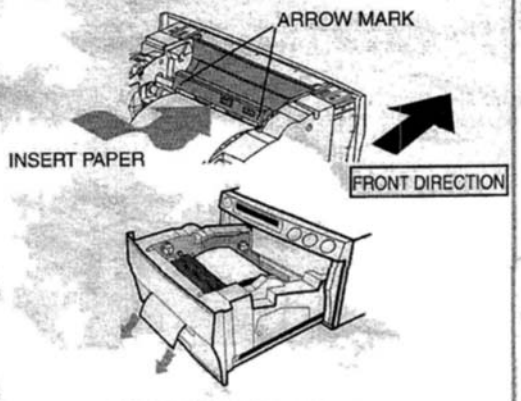
MEDIA INSTALLATION QUICK GUIDE

■OPEN PRINTING UNIT



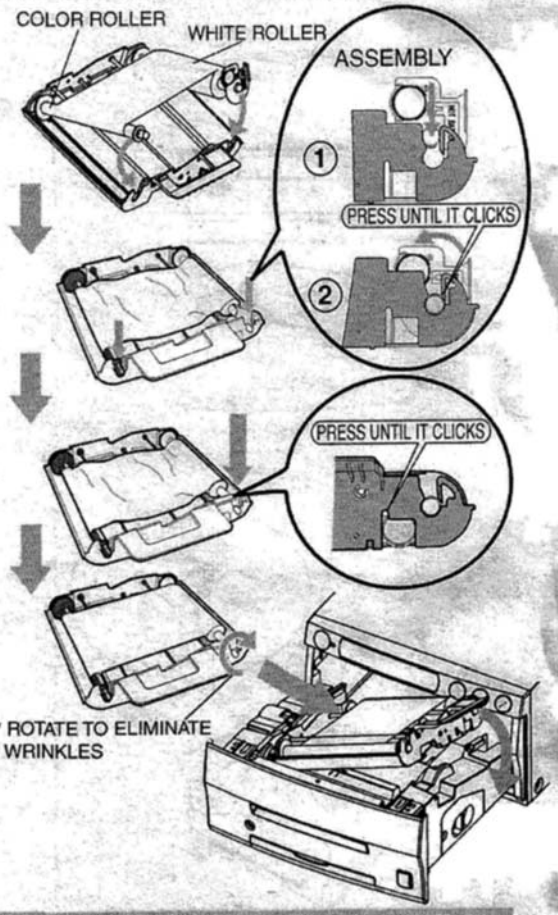
■PAPER LOARDING



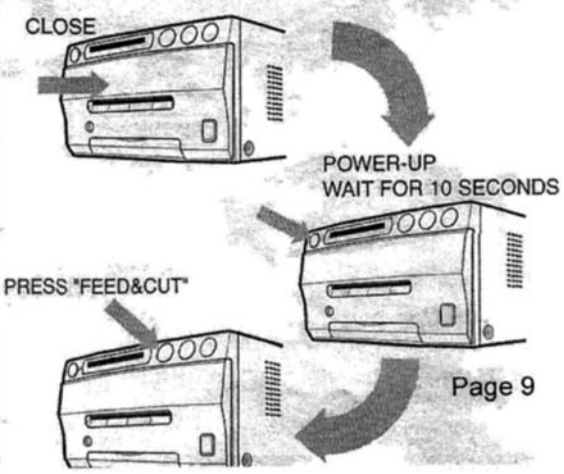


KEEP PAPER STRAIGHT AND TIGHT

■INK-SHEET/CARRIER ASSEMBLY AND LOARDING

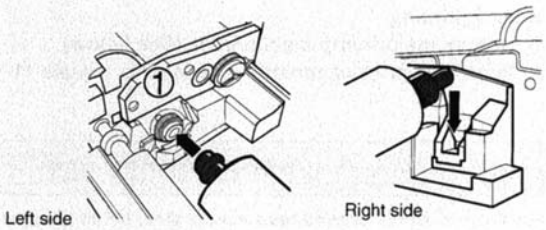


■MEDIA ALIGNMENT & INITIALIZATION



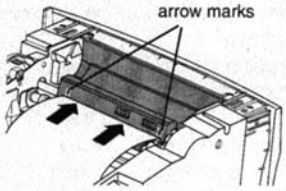
Page 9

2 Set the other side of roller without gear.

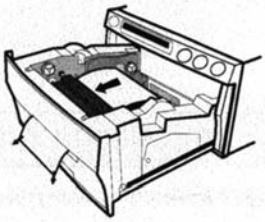


3 Remove the seal, and insert the edge of the print paper right below the roller cover with arrow marks towards the front panel.

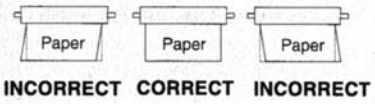
Make sure to insert the paper straight.



4 Feed the print paper through the paper outlet.



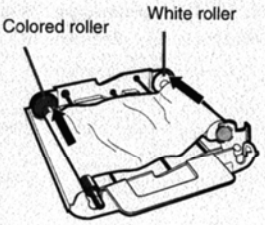
5 Pull both sides of the print paper to eliminate slack.



INSTALLATION OF INK SHEET

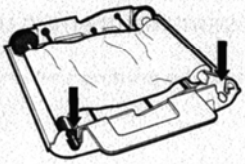
■ INSTALLING THE INK SHEET

Load the ink sheet roll to the ink cassette before inserting the ink cassette into the printer.



1 Insert the ink sheet rollers gear into the holes of the ink cassette.

Put the white roller (rolled with ink sheet) to the ink cassette first.
Then, insert the colored roller (take-up) to the ink cassette.

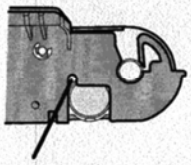


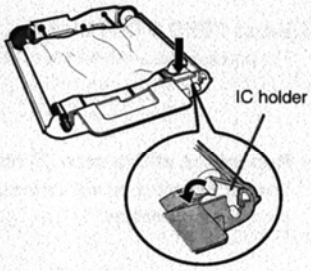
2 Put the other sides of rollers. Set IC at this time.

IC chip with the IC holder is attached to the ink sheet.
Set the IC holder to the ink cassette as shown right.

NOTE

- Do not remove the IC chip or IC holder from the ink sheet.
  Removal of the IC will stop the printer from functioning correctly.
- Set the projected part of the IC holder to the correct position as shown below.

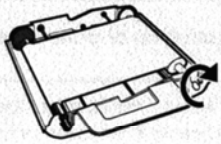




■ INSTALLING THE INK CASSETTE

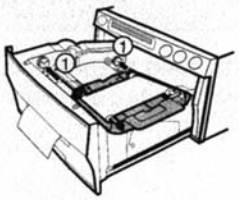
1 Eliminate any slack of the ink sheet.

Hold the colored roller and turn the white roller.



2 Insert the ink cassette with the ink sheet into its compartment.

Put the ink cassette into the printer drawer as shown ①. Then, set the other side (with handle) as shown right. When exchanging the ink cassette, remove it by holding the handle. (See page 19.)



■ INSERT THE PRINTING UNIT

1 Push the printing unit until it is locked into place.

2 After plugging the power cord, press POWER button on the front panel.

3 Press FEED & CUT button.

The print paper is automatically cut after feeding about 10 cm (4 inches).

4 Repeat the above step 3 once or twice.

Feeding the print paper will eliminate fingerprints and dust during handling. The printing unit is initialized.

NOTE

- Do not feed the print paper more than 2 times. Doing so will not allow the number of prints indicated on page 11 to be printed.

The installation of print paper and ink cassette is completed.

NOTE

An IC is built in the ink sheet. This is the IC chip, not a battery.
This IC can be thrown away as normal waste.

NOTE

Take the print paper one by one after completing printing. Pull out the tray completely when using it. If you fail to do so, paper jamming may occur.
Put the tray back after printing.

USAGE AND STORAGE OF PAPER SHEET SET

■ BEFORE PRINTING

- Fingerprints or dust on the paper's surface may degrade print quality and cause paper jams. Immediately after the paper is replaced, 2 images may be printed with a blank part due to fingerprints. Refer to Pages 11 - 12.
- When print paper is rapidly transferred from a cool place to a hot place, vapor or dew will be generated on the paper's surface causing paper jams or degraded print quality. Leave the print paper in the room to stabilize its temperature before use.
- When print paper and ink sheet run out during printing, the printing operation stops and the SHEET and/or PAPER lamp on the front panel will be lit or blink. Set new ink sheet or print paper. Refer to Pages 11-15.
- Excessive paper feeding will reduce total print count.

■ AFTER PRINTING

- When the image comes into contact with water, the print may be discolored.
- Fading may occur if the print-face is exposed to organic chemical agents which may affect print paper (e.g. alcohol, ester, ketone based).
- Fading will be accelerated upon contact with PVC-based materials (e.g. adhesive tapes, rubber erasers, etc.).
- Avoid storing prints in direct sunlight or places with high humidity.

■ STORAGE

- Leaving the print paper in contact with PVC-based materials causes color of print paper to change or staining to occur.
- Never store print paper in places that are close to heat sources, high humidity or dust.
  Keep print paper in a place where;
  Temperature : 5°C - 30 °C (41°F - 86°F)
  Humidity : 20 - 60%RH

TROUBLESHOOTING

INDICATION ON THE FRONT PANEL & COUNTERNEASURES

If for some reason printing is not possible or error occurs during printing, the indicators on the front panel will be lit.
In this case, follow the procedure described below.

○: lit ☼: blinks ●: not lit

ALARM	SHEET	PAPER	DATA	Causes	Countermeasures
●	●	○	●	Paper is used up. Paper is not installed.	• Set a new roll of paper. Refer to pages 11-13.
●	☼	●	●	The ink sheet is used up. IC chip is not installed. The data in IC chip cannot be read correctly. IC chip and the ink mark are not the same. A wrong media type is set.	• Replace the ink sheet with a new one. Refer to pages 13-15. • Use an ink sheet with the attached IC chip. • Set the attached IC chip on an ink sheet. • Use the correct ink sheet with IC chip. • Use correct IC chip and ink sheet.
●	○	●	●	The ink cassette is not installed.	• Install the ink cassette. Refer to pages 13-15.
●	☼	☼	●	The ink sheet and the print paper are not combined correctly.	• Use them in the correct combination.
☼	●	●	●	The temperature of the thermal head becomes too high.	• Wait until the ALARM indicator goes off. *Note
●	●	☼	○	The print paper is left at the print outlet.	• Remove the print paper.
○	●	○	○	Paper jam occurs.	• Refer to page 19 "Overcoming paper jams". Press FEED&CUT button.
○	●	●	●	Other defects.	• Press FEED&CUT button. In case of paper jam, refer to page 19 "Overcoming paper jams". If the status is not improved by carrying out this measure, consult your dealer.

*Note : When setting the continuous printing, this unit starts printing again after the indicator goes off.

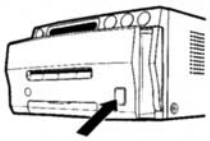
BEFORE CALLING FOR SERVICE

■ Use the following troubleshooting chart to try to resolve any apparent defect in operation. If you are unable to resolve the problem, unplug the power cord and contact your dealer.

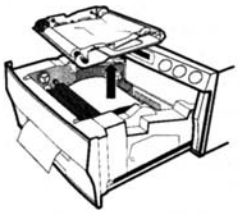
Symptom	Check and Remedy
No power (when POWER lamp does not illuminate)	Is the power cord plug disconnected from the outlet? →Connect the power cord plug to the outlet firmly. After tuning the power off, wait for approx. 2 minutes. Then turn on the power.
The image is not printed.	Is the image data sent to this unit? Is the print paper or ink sheet used up? Is the printing mechanism set correctly? →Check the status.
The stored image in the memory cannot be enlarged to fill the maximum print area.	Is the appropriate image data transferred? Is the S-size image data sent for L-size print paper? →Check the status.
COPY button does not work.	Is the image data transferred? → Send an image data. If the power is turned off and then turned on after sending the data, the COPY button does not work.
Though the print paper is not left at the print outlet, PAPER indicator blinks and DATA indicator goes on.	→ The sensor for detecting remaining paper may fail to work properly due to infrared light and so on. Set the mode switch No. 7 on the rear panel to ON.

OVERCOMING PAPER JAMS

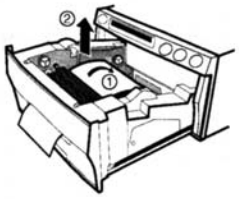
1 **Press OPEN button to pull out the printing mechanism.**
When it is not working, reset the power. Then try to press OPEN button again.



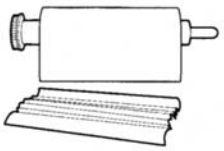
2 **Remove the ink cassette with ink sheet.**



3 **Remove the print paper as shown right.**



4 **Cut the defective part of the print paper with scissors.**

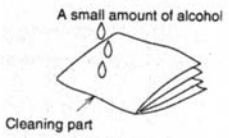


5 **Cut both edges of the print paper.**

6 **Install the print paper. (Refer to pages 11-13.)**

CLEANING

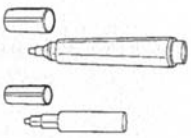
Cleaning as indicated below will help maintain stable printer operation and extend the printer's life.



How to hold tissue paper

Preparations

Alcohol (isopropyl alcohol)
Tissue paper (Fold in half about 4 times, and use the folded side to clean.)
Cotton buds
Cleaning kit (Option)*


Cleaner pen (Option)

Other : Cleaner pen (Option)*
*Please ask the dealer about options.

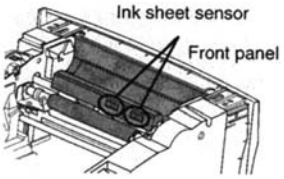
Make sure to turn off the power before cleaning.

1 Press OPEN button to pull the printing mechanism out.

2 Remove the ink cassette and print paper.

3 Wipe the ink sheet sensor.

Clean the parts circled in the right figure.
Carefully wipe with tissue paper etc. which is soaked in a small amount of alcohol.

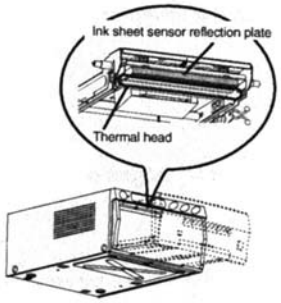


4 Wipe the ink sheet sensor reflection plate.

Clean the metal reflection plate.
Carefully wipe with tissue paper etc. which is soaked in a small amount of alcohol.

5 Wipe the head.

Cleaning the part under the thermal head which develops heat.
Wipe the head cleaning part carefully with tissue paper etc. which is soaked in a small amount of alcohol.

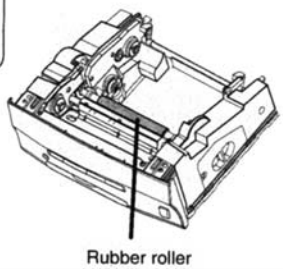


NOTE

- Do not damage the thermal head.
- When the symptom of the poor print quality is not corrected even if the head is cleaned, replacing the thermal head is required. Contact your dealer.
- Thermal head is hot right after printing. Wait until the head cools before cleaning the thermal head.

6 Clean the rubber roller.

Dust etc. can build up on the rubber roller after prolonged use. Carefully wipe with tissue paper etc. which is soaked in a small amount of alcohol.


Rubber roller

Description:	**FA Light Unit, Addition to RCII Cart**
Part Number:	**09-00-001 into 12-00-000**

Rev	ECO	Revision History	Author	Date
A		Released		09/12/03
B	2814	Update to current format and build	H. Crean	04/30/07

1.0 PURPOSE

1.1. To provide instructions on how to install an FA assembly as an option.

2.0 SCOPE

2.1. This work instruction provides the step by step procedure to install the FA assembly.

3.0 REFERENCE(S)

3.1.	FA light unit, Main assembly	09-00-001
3.2.	RCII Assembly Record Form	900300
3.3.	FA Accessory Kit Form, RCII	900209

4.0 EQUIPMENT AND TOOLING

4.1. Required for Assembly

4.1.1. 9/64” Allen wrench
4.1.2. 1/8” Allen wrench
4.1.3. Wire cutters

5.0 MATERIAL AND SUPPLIES

5.1. Two nylon tie wraps (optional)

6.0 ASSEMBLY PROCEDURE

6.1. Task No. 1 – Install FA option

6.1.1. Remove front drawer directly under the Light Box. To remover drawer:

6.1.1.1. Fully extend drawer.

6.1.1.2. Release and hold black detents on drawer slide.

6.1.1.2.1. One moves up and one moves down.

6.1.1.2.2. Arrows on slides indicate direction.

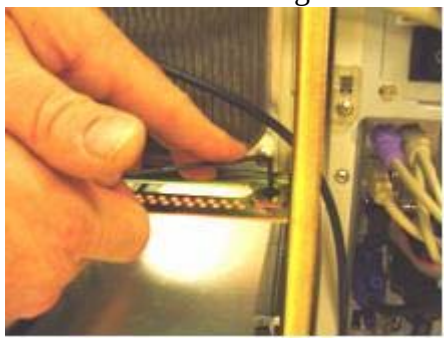
6.1.1.3. Pull drawer out.

6.1.1.3.1. A slight resistance will be felt.

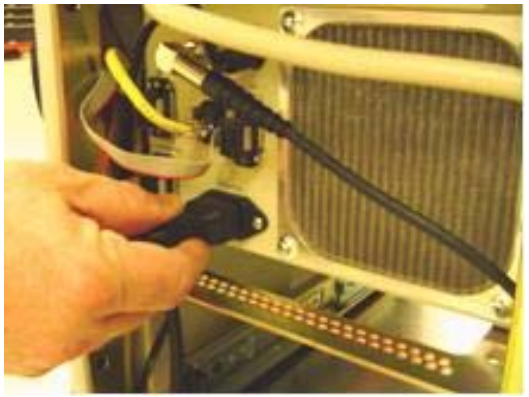
6.1.2. Remove rear panel, 7 screws, using 1/8” Allen wrench.

6.1.3. Remove the light box retainer bracket by removing 2 screws using a 9/64” allen wrench.

6.1.3.1. The retainer bracket holds the light box module in position.

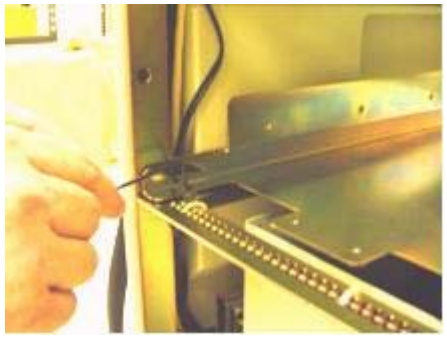


6.1.4. Unplug the light box power cord, and reroute the cord so that it does not block the path of the FA.



6.1.5. Remove the drawer tray (4 screws) using a 9/64” allen wrench.

6.1.5.1. Tray can be removed with rails attached.



6.1.6. Use cutters to remove 2 nylon ties holding FA power cord (existing to frame.

6.1.7. Mount the FA

6.1.7.1. Slide FA Unit into empty bay until it stops against the front panel.

6.1.8. Connect power cord to FA. Make sure that the power switch in on ("—").

6.1.9. Connect power cord to light box. Keep to left side, so as not to interfere with FA duct which is mounted on rear panel.

6.1.10. Install FA retainer bracket (12-03-049) with 8-32 screws (07-00-106) and #8 washers (07-00-316) using 9/64” allen wrench.

6.1.11. Install rear panel, 7 screws, using 1/8” allen wrench.

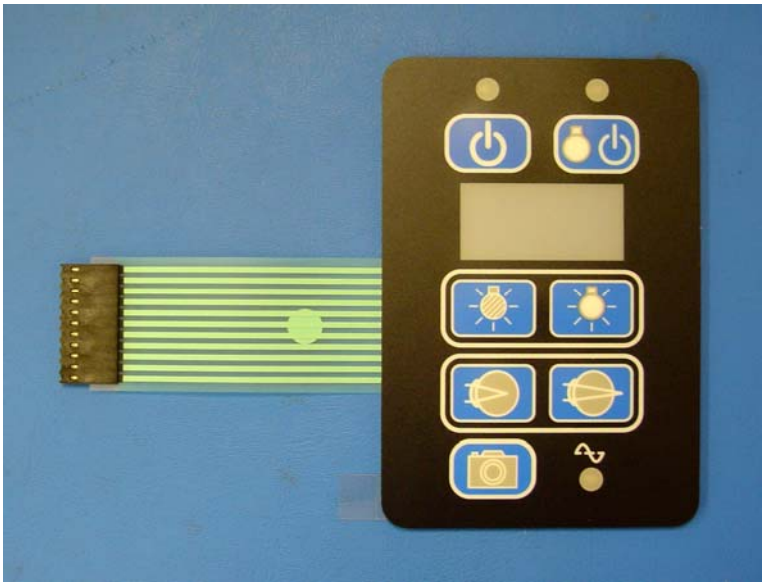
Note

Check that no cords (specifically light box power and FA power) are interfering with duct on rear panel. Technician may need to tie wrap these 2 cords together.

Procedure 800096 Revision B, Membrane control panel replacement.

Rev	ECO	Revision History	Date	Approved
A	2360	Release	April 20, 2004	G. Sprehn
B	2468	Changed to membrane panel without resistors and membrane PCB Rev. B with resistors October 6, 2004 beginning with RetCam II SN: 2072. Also added membrane panel adapter board PN 12-04-029 for use with Rev. A membrane PCB's.	Feb. 1, 2005	G. Sprehn

Procedure 800096 Revision B, Membrane control panel replacement.



Procedure: Replacement of the membrane control panel in the RetCam II imaging system.

Contains: Listing of tools and supplies along with step by step instructions on the replacement of the membrane.

Tools: Small slotted screwdriver or knife –
for removal of membrane control panel.
Hex wrenches – 3/32 and 5/64 inch
Philips screwdriver - #2

Parts: Replacement membrane control panel PN 12-00-015.
Membrane PCB PN 12-00-013 if needed.
Membrane Panel Adapter PCB PN 12-04-029 if needed.

Supplies: Drawer liners – in printer and front storage drawers.
Electrical tape if needed.

Outline: 1.0 Removal of membrane.
1.0A If membrane PCB needs to be replaced.
2.0 Installation of membrane.

Notes: The dimensions of the membrane control panel were 2 ½ x 4 ¼ inches for RetCam II systems SN 2001 - 2010.
The panel was resized to ~ 3 x 5 ¼ inches starting with SN 2011.
The dimensions should be verified when ordering this part.

1.0 Removal of membrane.

1.1 **Disconnect the power cord at the back of the base.**

1.2 Open the printer drawer and disconnect the power and USB cables from the printer.

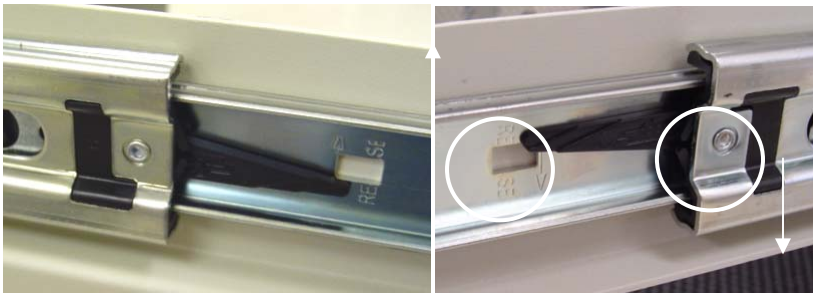
1.3 Lift the printer out of the drawer.

1.4 Remove the printer drawer.

1.4.1 Extend the drawer fully open.

1.4.2 Locate the black locking tabs on both sides of the drawer gliders.

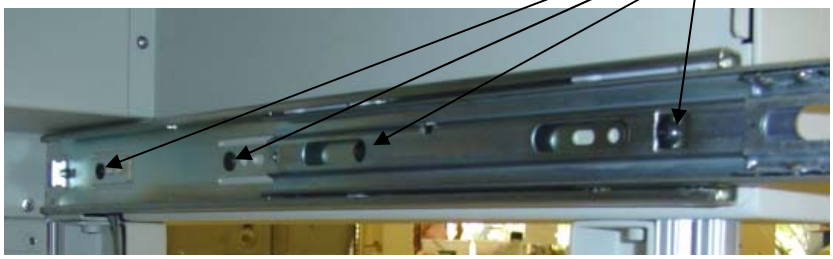
1.4.3 Pull the left tab upward and the right tab downward as you pull the drawer out of the system.



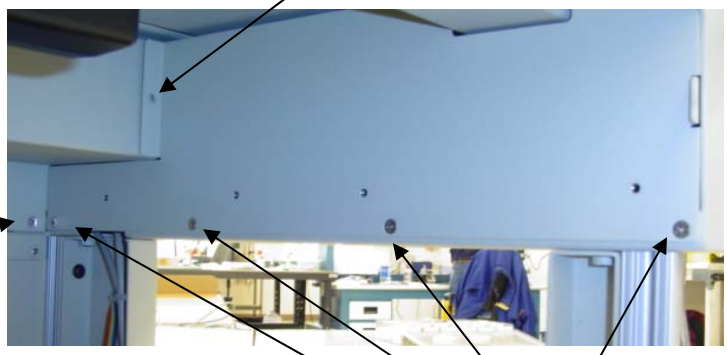
1.5 Place drawer liners inside the RetCam II chassis to prevent screws removed from falling down. Use the liners from the printer and front storage drawers.

1.6 Remove the printer transformer from the underside of the top cover.

1.7 Remove the glider tracks from the inner panels on the system.
1.7.1 Extend the gliders as necessary to expose the screws.
Using a 3/32 inch hex wrench remove 4 screws from each side.



1.8 Remove the upper screws securing the side panels to the front cover using a 5/64 inch hex wrench. There is one screw on each side



Front access panel screw

1.9 Remove the side panel by removing the 4 philips head screws on the lower edge of the panel and any screws holding the side panel to the front panel.
1.10 Pull out on the membrane cable to detach it.

The membrane control panel and membrane PCB are sensitive to electrostatic discharge.

Wear an ESD strap grounded to the RetCam II frame.

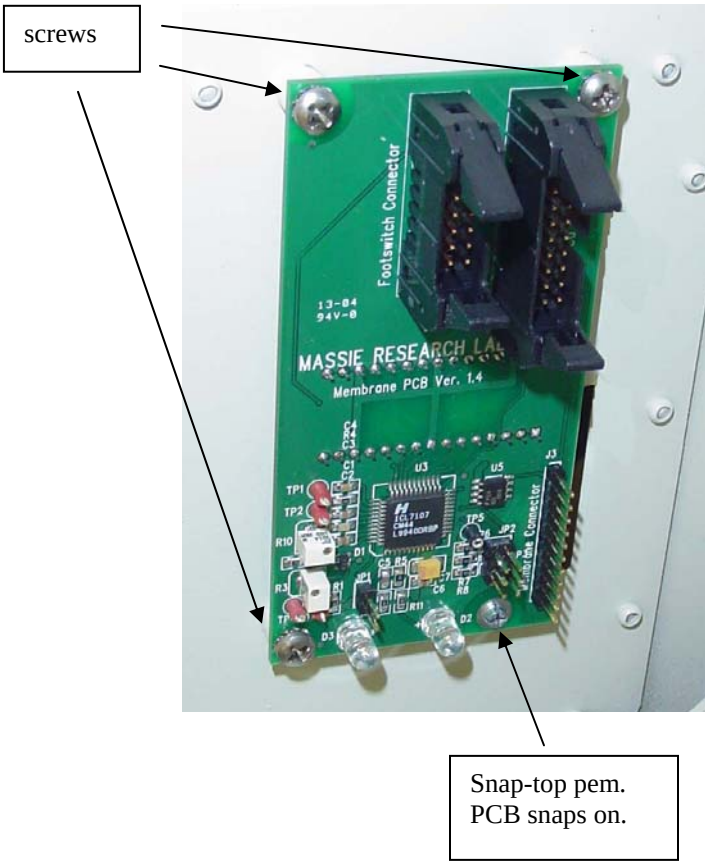
Membrane cable

1.11 Push the membrane out of the top cover assembly.

1.12 Remove the membrane and any adhesive which may be left on the chassis.

1.0A If membrane PCB needs to be replaced.

1.1A Remove any screws holding the PCB to the frame.



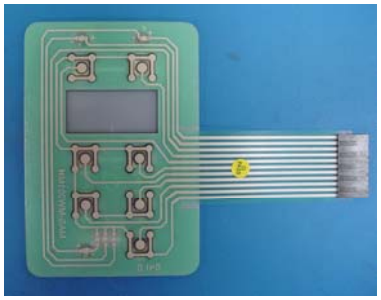
1.2A Pull out the PCB.
1.3A Insert the replacement PCB and fasten with screws.

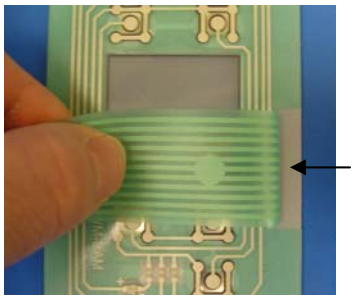
2.0 Installation of membrane.

Wear an ESD strap grounded to the RetCam II frame.

The membrane control panel and membrane PCB are sensitive to electrostatic discharge.

2.1 Remove the membrane from the packaging.
2.2 Remove the paper backing from the membrane and install it on the RetCam II system.



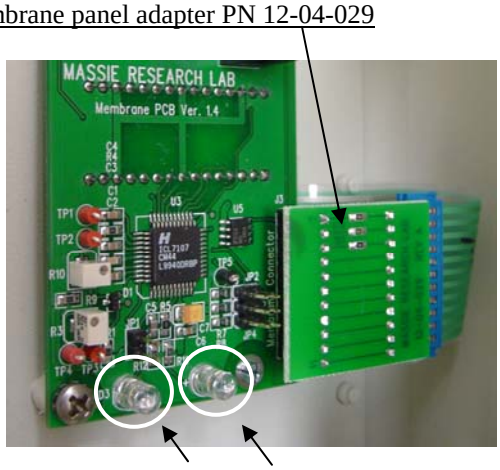


remove the adhesive pad

2.3 Connect the membrane cable to the PCB

2.3 A

For Ver 1.4 Rev A PCB and Rev B membrane control panel use membrane panel adapter PN 12-04-029



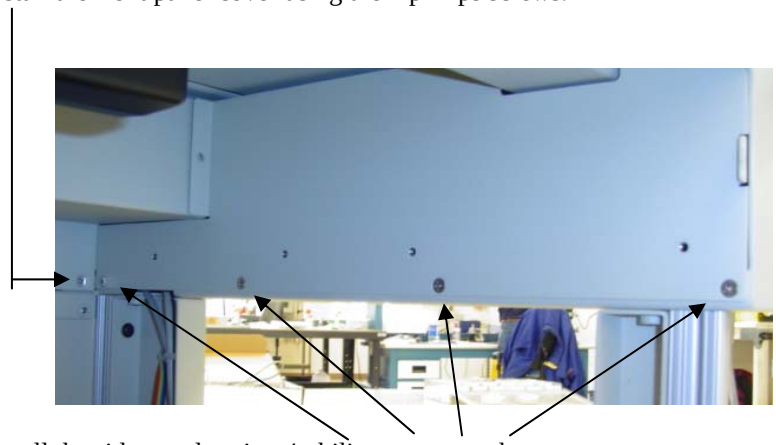
Rev A PCB has White LED's

2.3 B

For Rev B PCB and Rev B membrane control panel

2.4 Reconnect the cables from the footswitch and lightbox. The cable design is dedicated to the connector so the cables can not be switched.

2.5 Install the front panel cover using the 2 philips screws.



2.6 Install the side panels using 4 philips screws each.
2.7 Secure the 2 hex screws holding the side panels to the front panel.

2.8 Install the side glider tracks.
2.9 Resecure the printer transformer to the underside of the top cover.
2.10 Remove the drawer liners.
2.11 Install the printer drawer.
2.12 Connect the power and USB cables to the report printer.
2.13 Connect the power cord to the system and verify the power switch on the base is turned on.

Appendix 4

Field Service

Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

Rev	ECO	Revision History	Date	Approved
A	2441	Release	December 6, 2004	G. Sprehn
B	2539	Change header logo to Clarity Medical Systems	September 28, 2005	G. Sprehn

Appendix 4

Field Service

Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

Procedure:

Replacing the front caster on a RetCam II

Supplies:

Loctite 242
Caster PN 12-01-050
4 - Washers PN 07-00-235
.38 x .87 x .07T, ZN
4 - Screws PN 07-00-308
5/16-18 x .75L, SS

Tools needed:

for front wheel
3/16” Hex wrench

Outline:

1.0 Preparation
2.0 Replacing a front caster
3.0 Restore to the original condition.

Appendix 4

Field Service

Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

1.0 Preparation

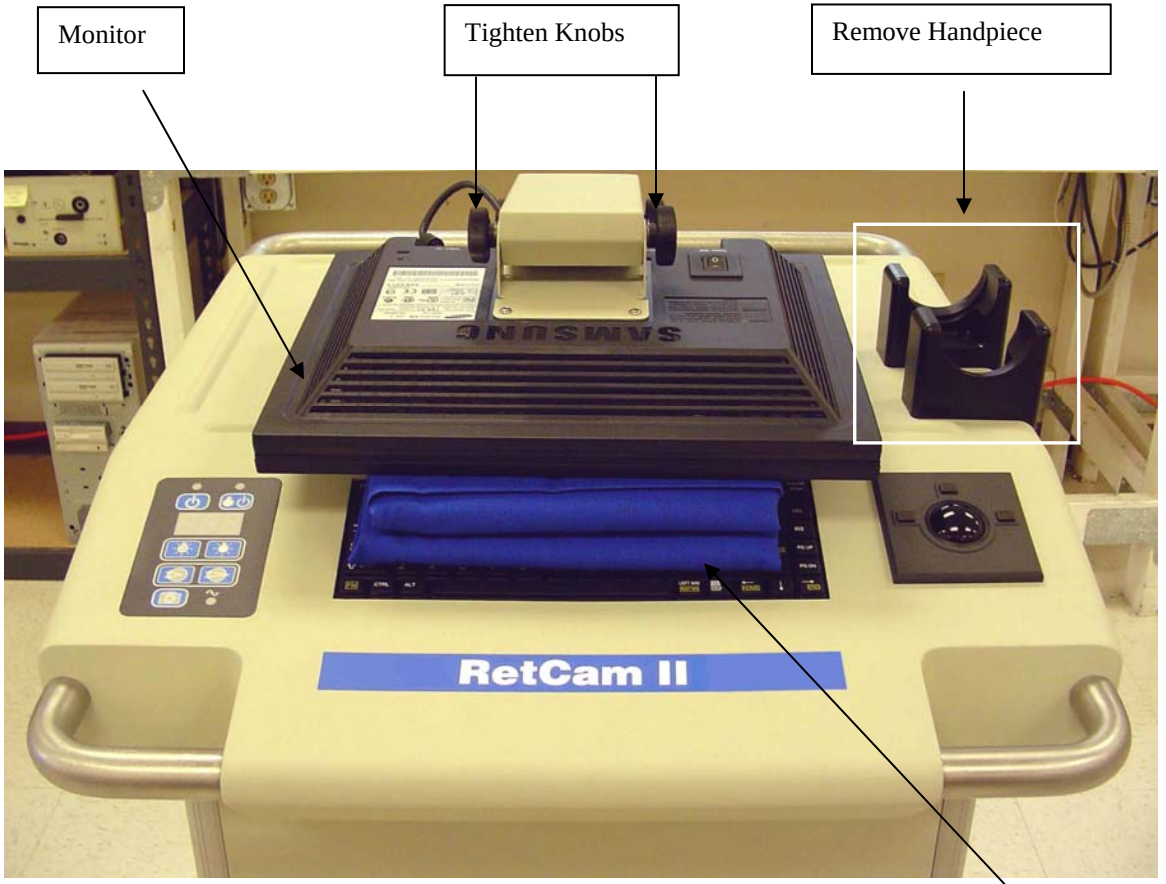
1.1 Turn the system power off.
1.2 Unplug the system from the outlet.

1.3 Disconnect and remove the handpiece.
1.4Disconnect and remove the report

printer.

1.5 Remove all items from the drawers.

1.6 Secure the monitor.



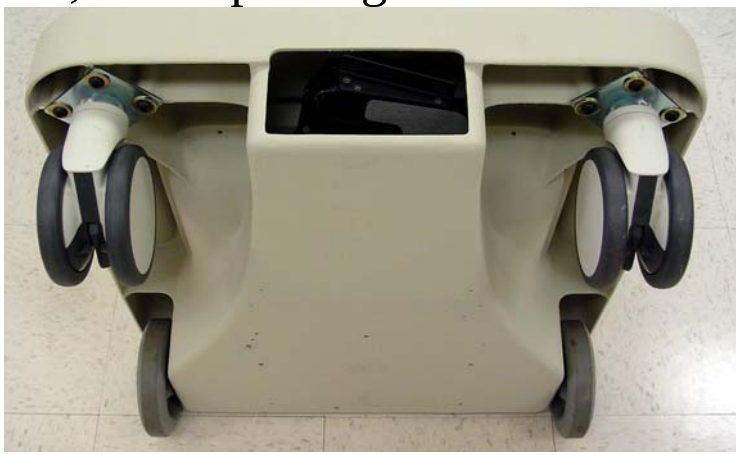
Appendix 4

Field Service

Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

2.0 Replacing a front wheel

2.1 With two people, slowly tilt back the system until it rests on its rear handle.



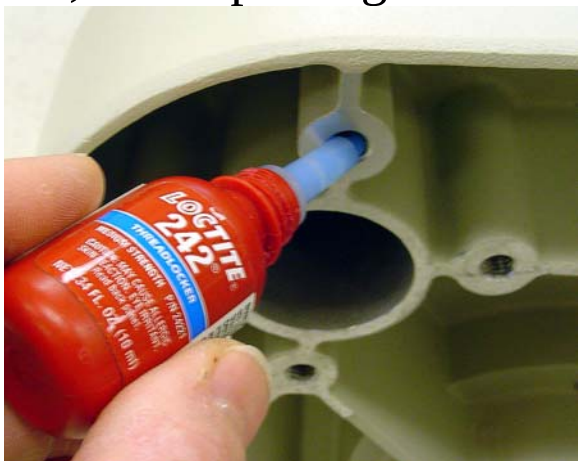
2.2 With the 3/16” hex wrench remove the four screws and washers holding the caster to the base and remove the caster.

Appendix 4

Field Service

Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

2.3 Place a drop of Loctite 242 in each of the four threaded holes for the base wheel.



2.4 Install the replacement caster.
Caster PN 12-01-050

2.5 Check that the caster is mounted securely by gripping the caster and trying to move it; it should not move. If the caster does move then tighten the screws. Also check for the wheel rolling and spinning and the ability to lock and unlock it.

Appendix 4

Field Service
Method 800099 Revision B, for Replacing the Front Casters on a RetCam II

3.0 Restore to the original condition.

3.1 With two people, upright the system.

3.2 Restore the monitor to its original position.

3.3 Install the handpiece.
3.4 Install the report printer.
3.5 Replace any items removed from the drawers.

3.6 Plug the system in.
3.7 Power the system on.

Procedure 800111 Revision A, Trackball replacement.

Front view of installed trackball.

Rear view of trackball in packaging

Rev.	ECO	Revision History	Date	Approved
A	2456	Release	Feb. 1, 2005	G. Sprehn

Procedure: Replacement of the Trackball in the RetCam II imaging system.

Contains: Listing of tools and supplies along with step by step instructions on the replacement of the Trackball.

Tools: Hex wrenches – 3/32, 5/64 inch and 1.5 mm
Philips screwdriver - #2
Sidecutters (wire cutters for wire ties)

Supplies: Drawer liners – in printer and front storage drawers.
Nylon cable ties – standard 4” or more length x .10” width

Outline: 1.0 Removal of Trackball.
2.0 Installation of Trackball.

1.0 Removal of trackball.

1.1 **Disconnect the power cord at the back of the base.**

1.2 Open the printer drawer and disconnect the power and USB cables from the printer.

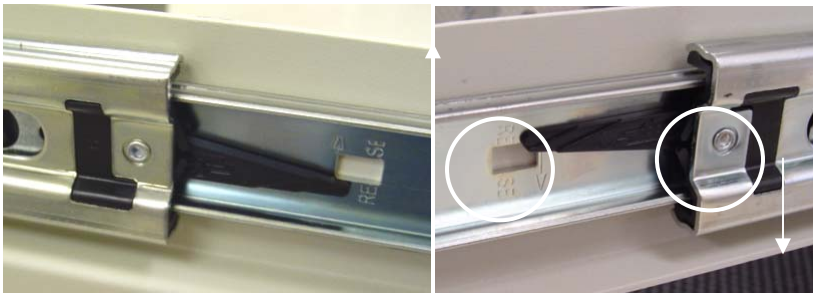
1.3 Lift the printer out of the drawer.

1.4 Remove the printer drawer.

1.4.1 Extend the drawer fully open.

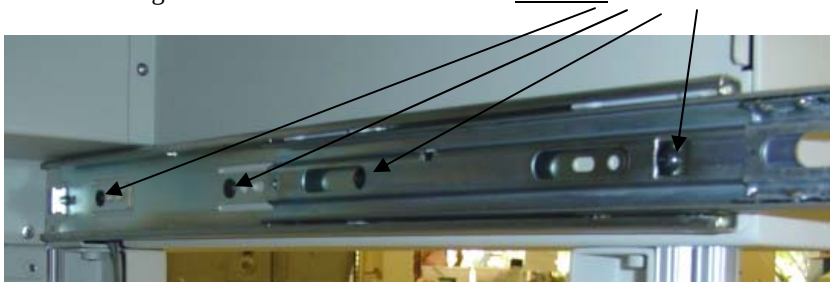
1.4.2 Locate the black locking tabs on both sides of the drawer gliders.

1.4.3 Pull the left tab upward and the right tab downward as you pull the drawer out of the system.

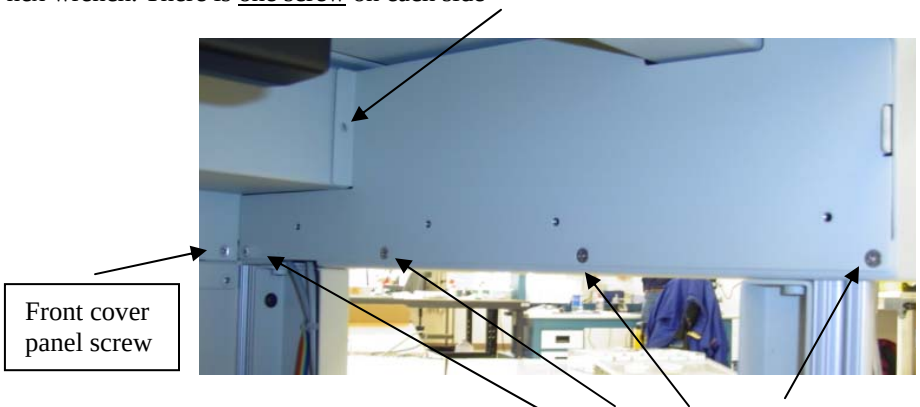


1.5 Place drawer liners inside the RetCam II chassis to prevent screws removed from falling down. Use the liners from the printer and front storage drawers.

1.6 Remove the glider tracks from the inner panels on the system.
1.6.1 Extend the gliders as necessary to expose the screws.
Using a 3/32 inch hex wrench remove 4 screws from each side.



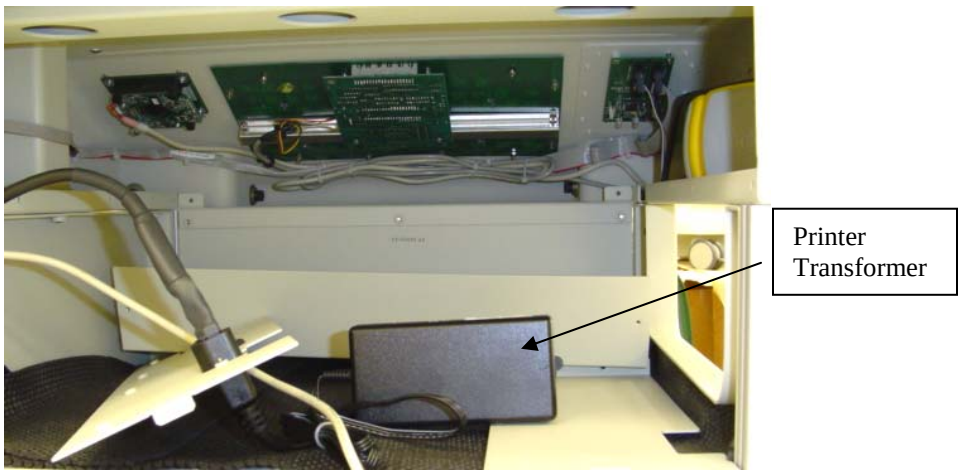
1.7 Remove the upper screws securing the side panels to the front cover using a 5/64 inch hex wrench. There is one screw on each side



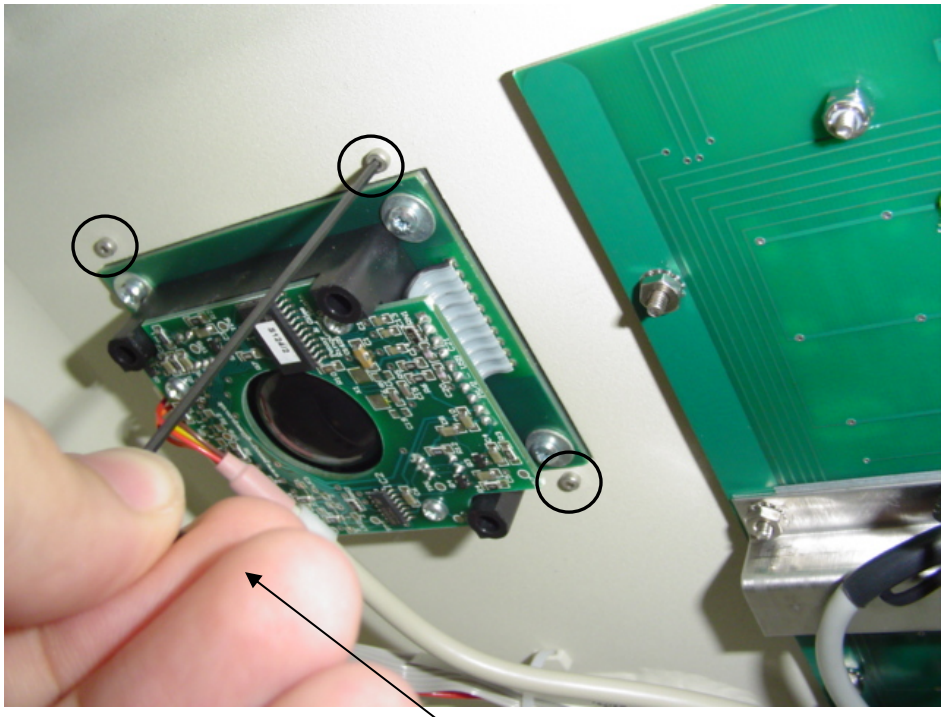
1.8 Remove the side panels by removing the 4 philips head screws on the lower edge of each panel. The panel on the left has cabling attached,
lower this out of the way.

1.9 Remove the front cover panel by removing the 2 philips screws located on the lower corners of the panel.

1.10 The printer power transformer is attached to the underside of the top panel with thick tape. Gently pry this loose and set it aside.



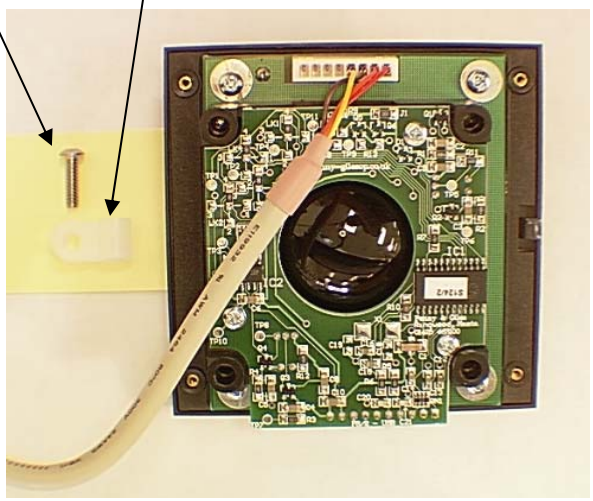
1.11 Using the 1.5 mm hex wrench, remove the 4 screws that fasten the trackball to the RetCam II chassis.



The fourth screw is in the hidden corner.

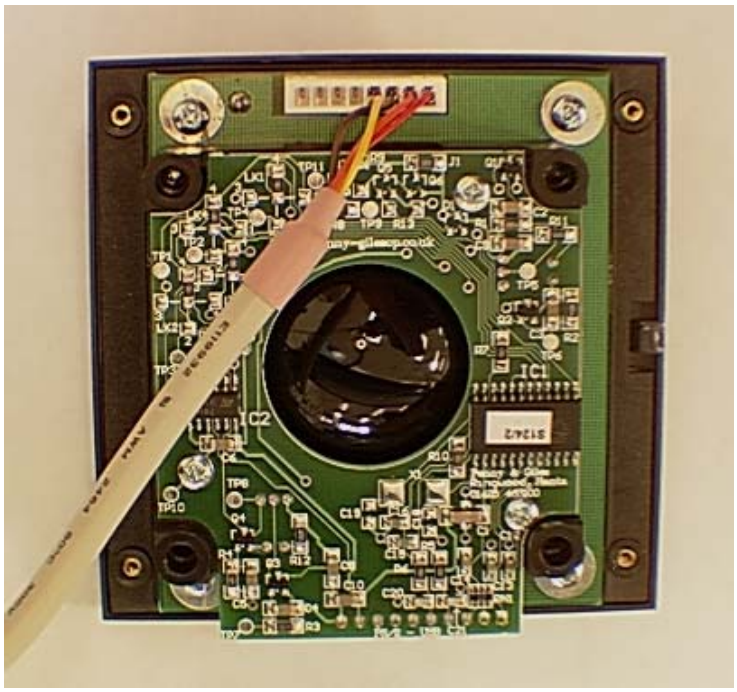
1.12 Cut the wire ties holding the trackball cable to the RetCam II chassis.
1.13 Disconnect the trackball cable from the computer.

1.14 Remove the screw and cable clip from the trackball.
Keep the screw and cable clip for the trackball yet to install.

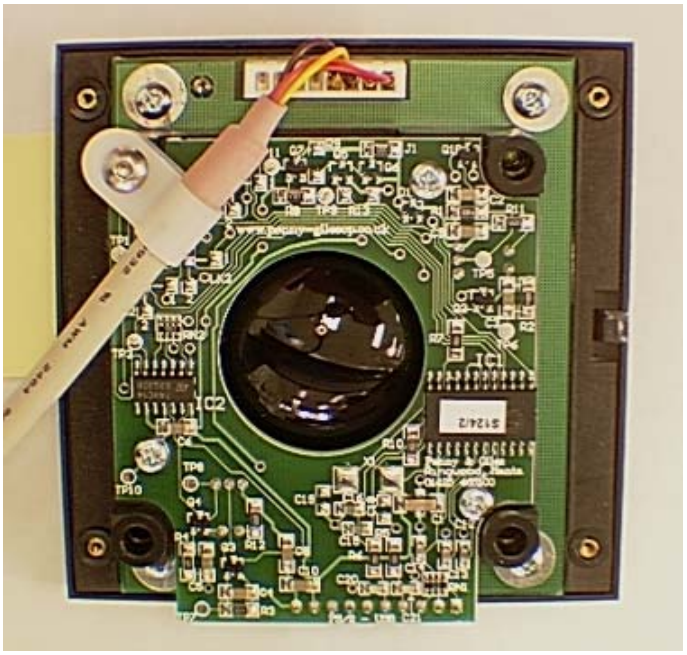


2.0 Installation of Trackball.

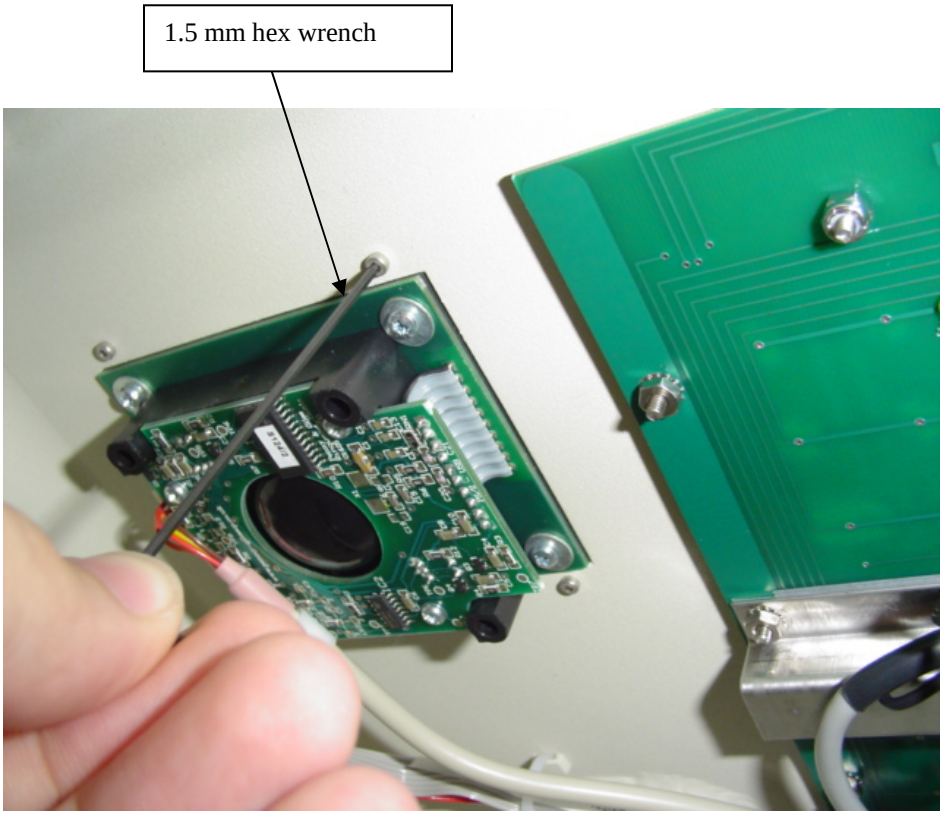
2.1 Remove the trackball from the packaging.
2.2 Insert the cable into the connector.



2.3 Secure the cable to the trackball mount with the screw and cable clip from the replaced trackball.

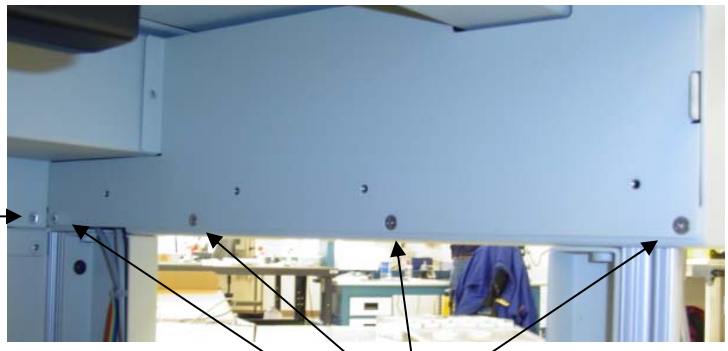


2.4 Mount the trackball to the chassis.



2.5 Route the trackball cable to the computer and connect it.

2.6 Wire tie the trackball cable to the RetCam II chassis.
2.7 Cut off the excess nylon tie.
2.8 Install the front panel cover using the 2 philips screws.



2.9 Install the side panels using 4 philips screws each.
2.10 Secure the 2 hex screws holding the side panels to the front panel.

2.11 Install the side glider tracks.
2.12 Resecure the printer transformer to the underside of the top cover.
2.13 Replace the drawer liners.
2.14 Install the printer drawer.
2.15 Connect the power and USB cables to the printer.
2.16 Connect the power cord to the system and verify the power switch on the base is turned on.

Procedure 800134 Revision A, TRAXSYS Trackball cleaning.

Front view of installed trackball.

Rev.	ECO	Revision History	Date	Approved
A	2490	Release	08 Apr 05	G. Sprehn

Procedure: Cleaning of the Trackball in the RetCam II imaging system.

Contains: Listing of tools, equipment and supplies along with step by step instructions on the cleaning of the TRAXSYS Trackball.

Tools: Hex wrenches – 3/32, 5/64 inch and 1.5 mm
Philips screwdriver - #2
Sidecutters (wire cutters for wire ties)

Equipment ESD (ElectroStatic Discharge) station
Wriststrap with grounding cable

Supplies: Drawer liners – in printer and front storage drawers.
Nylon cable ties – standard 4” or more length x .10” width
Isopropyl Alcohol is required – do not use other solvents.
Double sided foam tape for printer transformer.

Outline: 1.0 Removal and cleaning of the Trackball.
2.0 Reinstallation of the cleaned Trackball.

1.0 Removal and cleaning of the Trackball.

1.1 **Disconnect the power cord at the back of the base.**

1.2 Open the printer drawer and disconnect the power and USB cables from the printer.

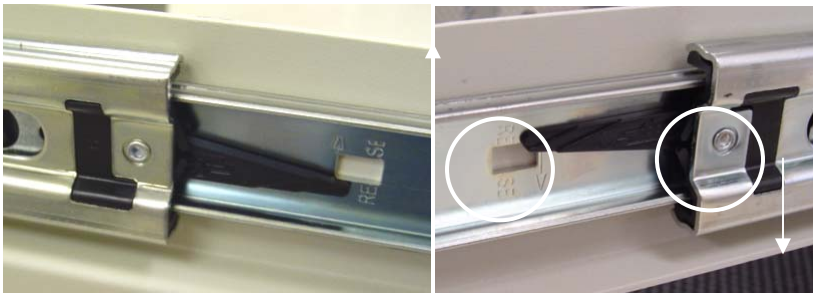
1.3 Lift the printer out of the drawer.

1.4 Remove the printer drawer.

1.4.1 Extend the drawer fully open.

1.4.2 Locate the black locking tabs on both sides of the drawer gliders.

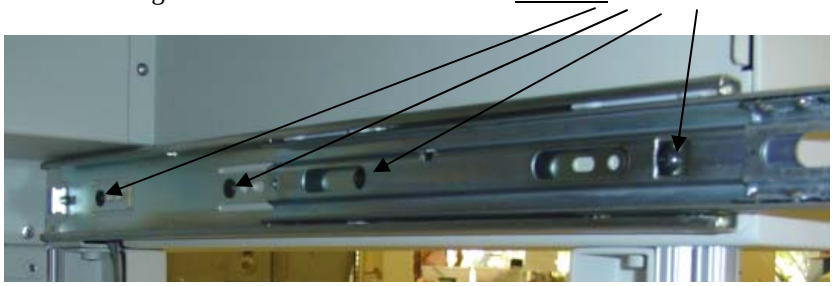
1.4.3 Pull the left tab upward and the right tab downward as you pull the drawer out of the system.



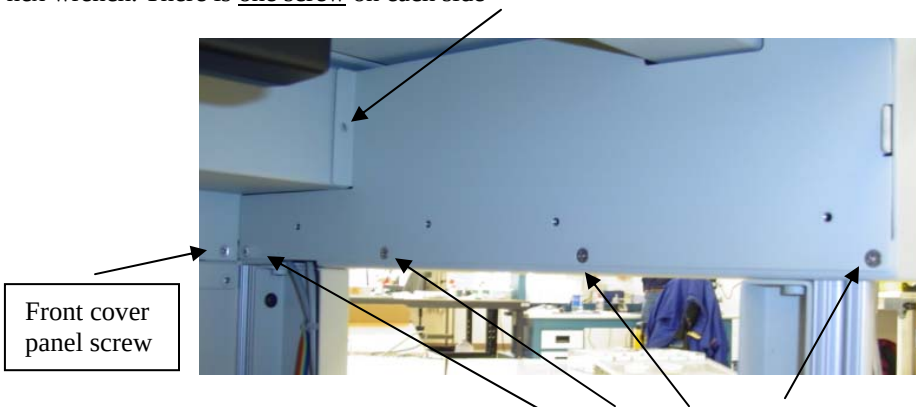
1.5 Place drawer liners inside the RetCam II chassis to prevent screws removed from falling down. Use the liners from the printer and front storage drawers.

1.6 Remove the glider tracks from the inner panels on the system.

1.6.1 Extend the gliders as necessary to expose the screws.
Using a 3/32 inch hex wrench remove 4 screws from each side.



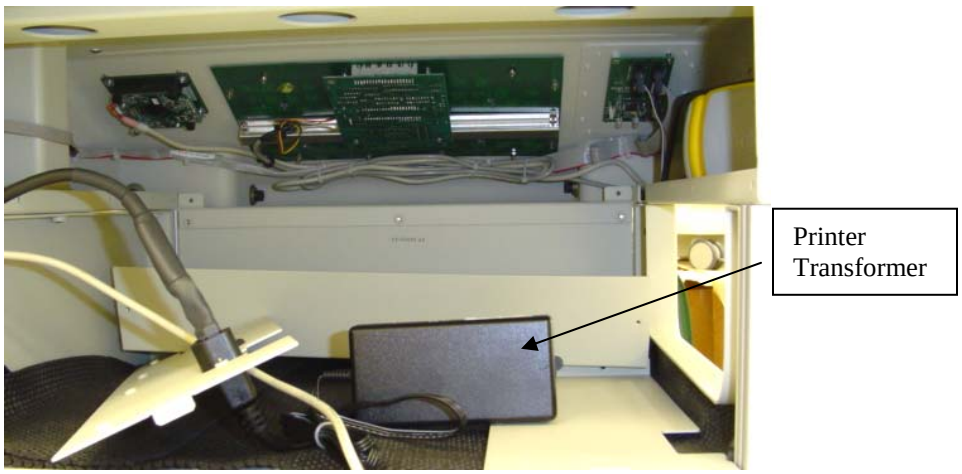
1.7 Remove the upper screws securing the side panels to the front cover using a 5/64 inch hex wrench. There is one screw on each side



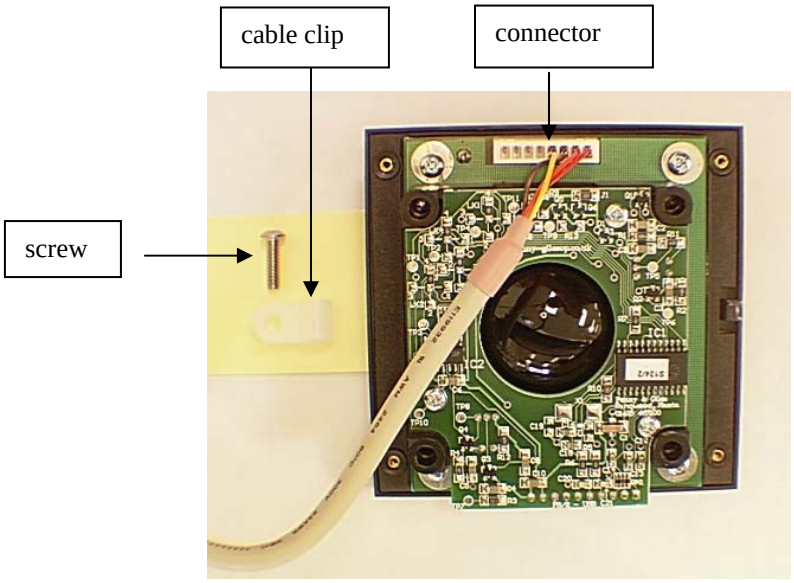
1.8 Remove the side panels by removing the 4 philips head screws on the lower edge of each panel. The panel on the left has cabling attached,
lower this out of the way.

1.9 Remove the front cover panel by removing the 2 philips screws located on the lower corners of the panel.

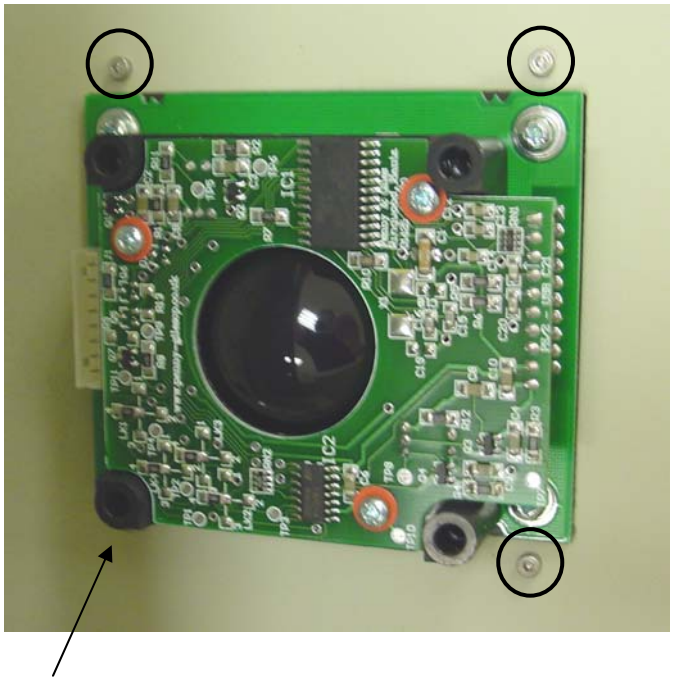
1.10 The printer power transformer is attached to the underside of the top panel with thick tape. Gently pry this loose and set it aside.



1.11 Cut the first few wire ties holding the trackball cable to the RetCam II chassis.
1.12 Using a wriststrap with a cable grounded to the system remove the screw, cable clip, and connector from the trackball.



1.13 Using the 1.5 mm hex wrench, remove the 4 screws that fasten the trackball to the RetCam II chassis.

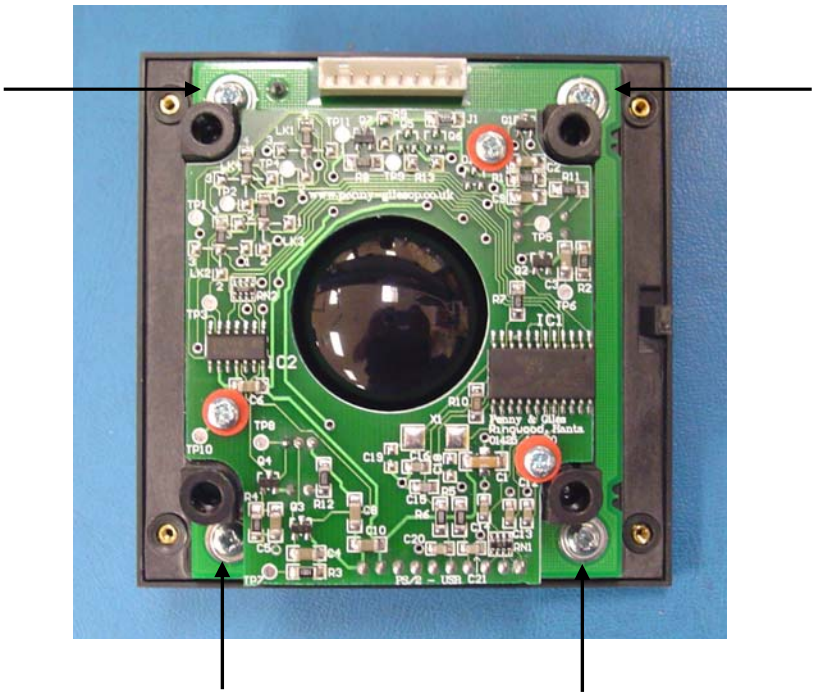


The fourth screw, which is not shown, is in the corner.

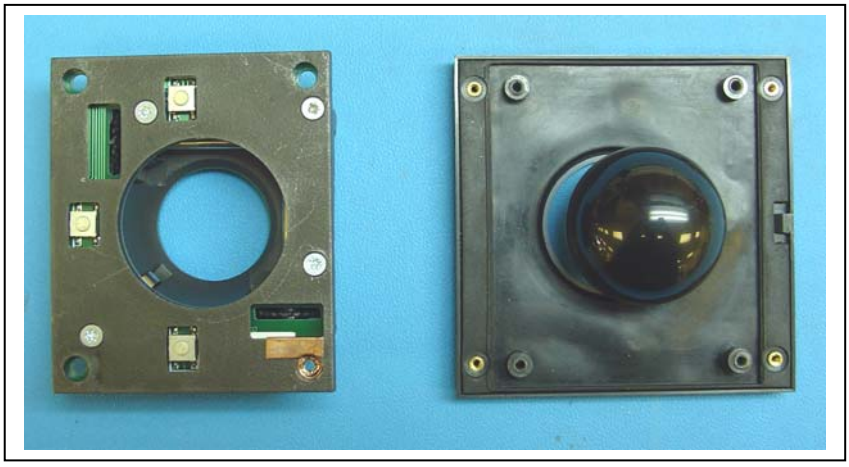
1.14 Remove the trackball from the top cover.

1.15 The trackball assembly has a PCB (Printed Circuit Board) that is sensitive to static electricity. The cleaning should be done at an ESD station.

1.16 Remove the four philips screws holding the PCB to the trackball assembly.

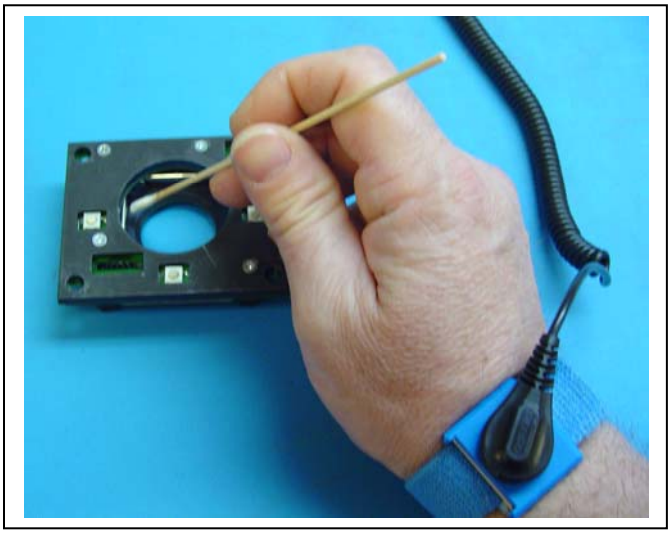


1.17 Separate the two halves.



1.18 Clean the ball with Isc

1.19 Clean the rollers with a cotton swab dipped in isopropyl alcohol



1.20 Reassembly the two halves.

2.0 Reinstallation of the cleaned Trackball.

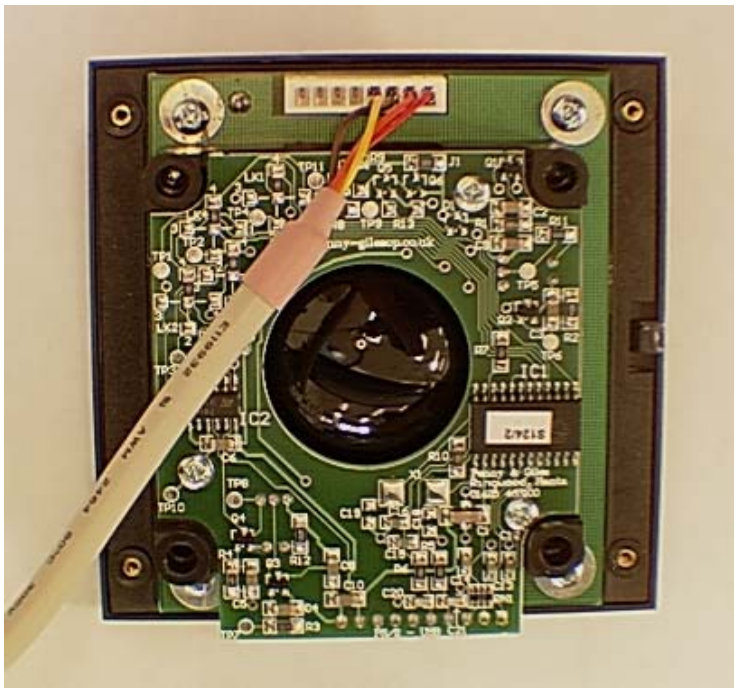
- ❖ This is to be done utilizing ESD practices for static sensitive devices.

2.1 Insert the cleaned trackball into the top cover of the RetCam II system.

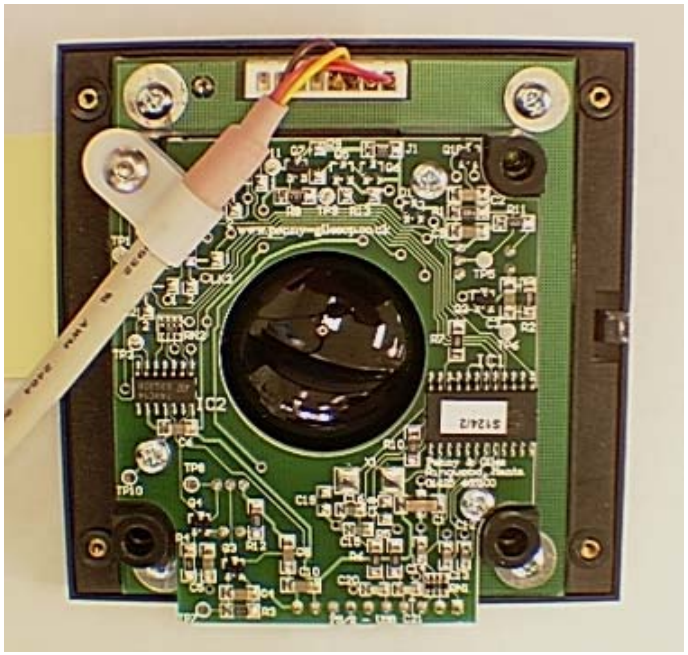
2.2 Mount the trackball to the chassis.

The fourth screw, which is not shown, is in the corner.

2.3 Insert the cable into the connector.

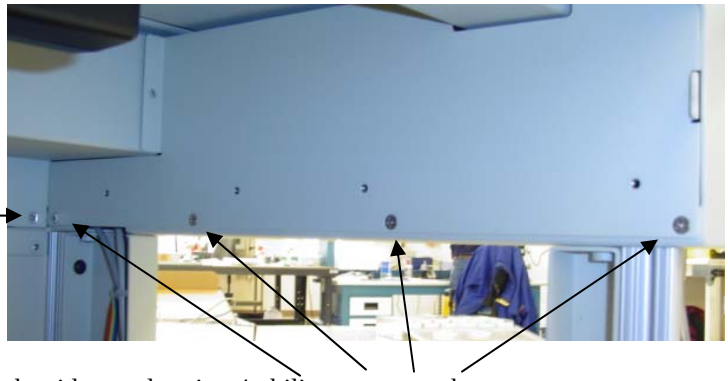


2.4 Secure the cable to the trackball mount with the screw and cable clip.



2.5 Wire tie the trackball cable to the RetCam II chassis.

2.6 Cut off the excess nylon tie.
2.7 Install the front panel cover using the 2 philips screws.



2.8 Install the side panels using 4 philips screws each.
2.9 Secure the 2 hex screws holding the side panels to the front panel.

2.10 Install the side glider tracks.
2.11 Resecure the printer transformer to the underside of the top cover.
2.12 Replace the drawer liners.
2.13 Install the printer drawer.
2.14 Connect the power and USB cables to the printer.
2.15 Connect the power cord to the system and verify the power switch on the base is turned on.

Appendix 7

Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

Rev	ECO	Revision History	Date	Approved
A	2537	Release	8/22/05	G. Sprehn

Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

Procedure:

This is a procedure for replacing the computer in a RetCam II system.

Supplies:

Computer

PN: 03-00-016

Tools needed:

1/8” Hex wrench
3/32” Hex wrench
Philips screwdriver

Outline:

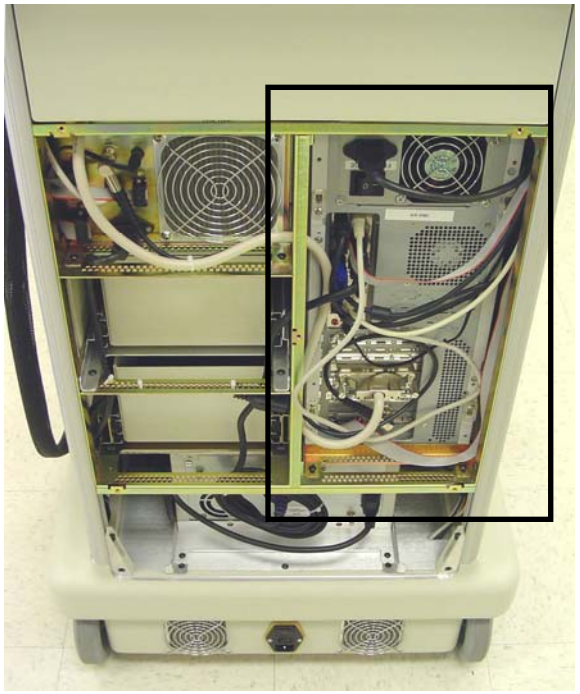
1.0 Preparation
2.0 Remove computer
3.0 Install replacement computer
4.0 Restore to the original condition.

Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

1.0 Preparation

1.1 Turn the system power off.
1.2 Unplug the system from the outlet.
1.3 Lock the front casters.
1.4 Remove the rear cover. There are 7 screws holding the back panel to the system. Using a 1/8” hex wrench, remove these screws.



Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

2.0 Remove computer

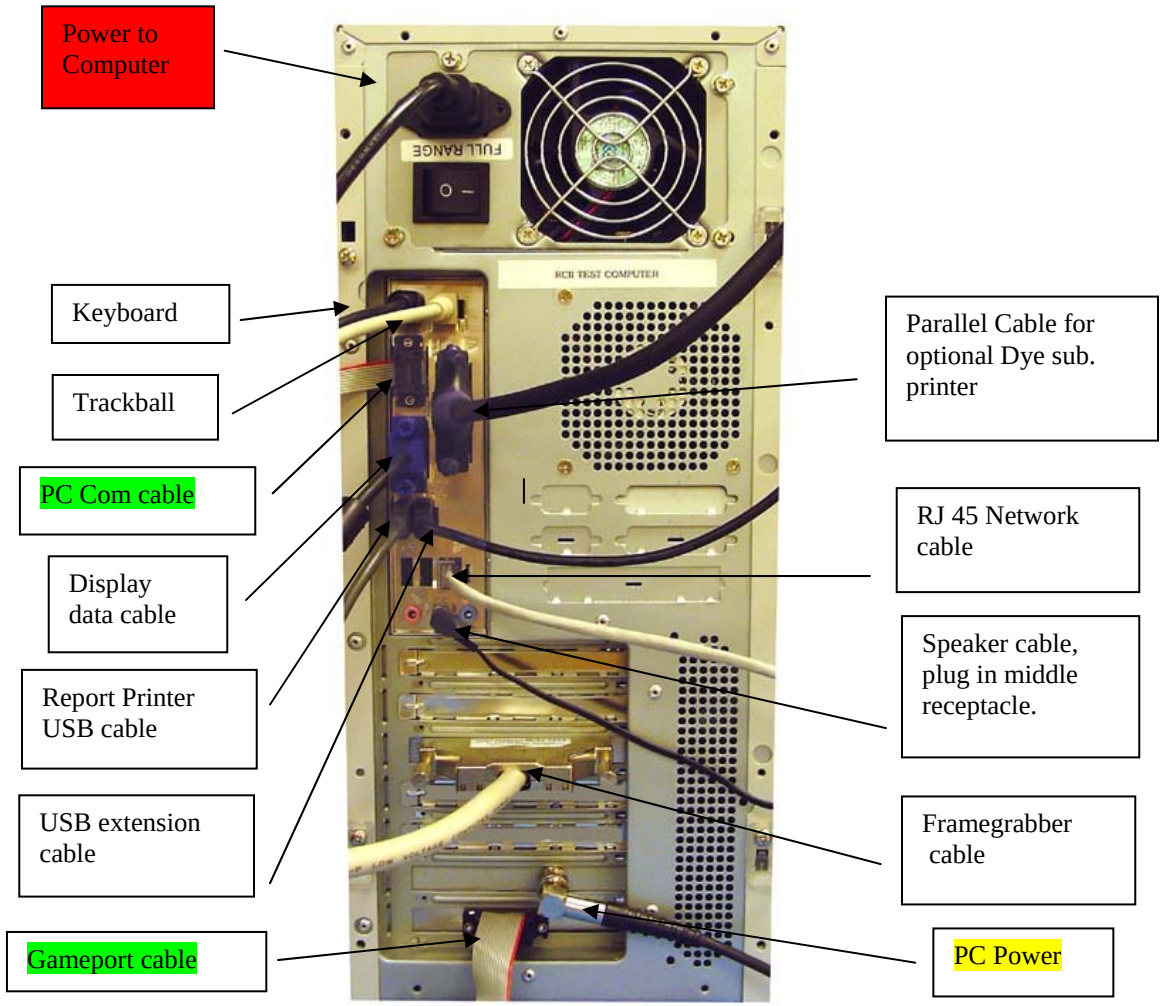
2.1 Disconnect the following cables:
- Power to Computer
- Keyboard
- Trackball
- Report Printer USB cable
- USB extension cable
- Speaker cable
- RJ 45 Network cable
  (push in tab then pull out)

2.2 Unscrew and disconnect:
- Display data cable
- Framegrabber cable
- (Parallel Cable for optional Dye sub. printer)

2.3 Remove screws using a 3/32” hex wrench and disconnect:
- PC Com cable
- Gameport cable

2.4 Remove the PC Power cable:
This is a BNC connecter; to remove this, turn the connector counter clockwise to disengage the locking pins and disconnect.

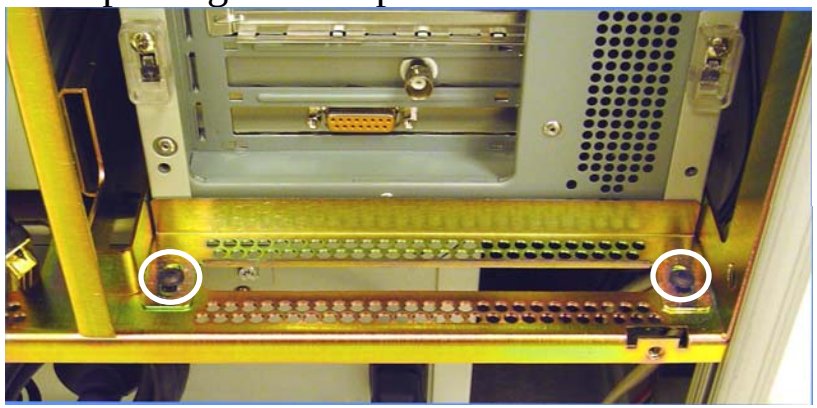
RetCam II Computer (rear view)



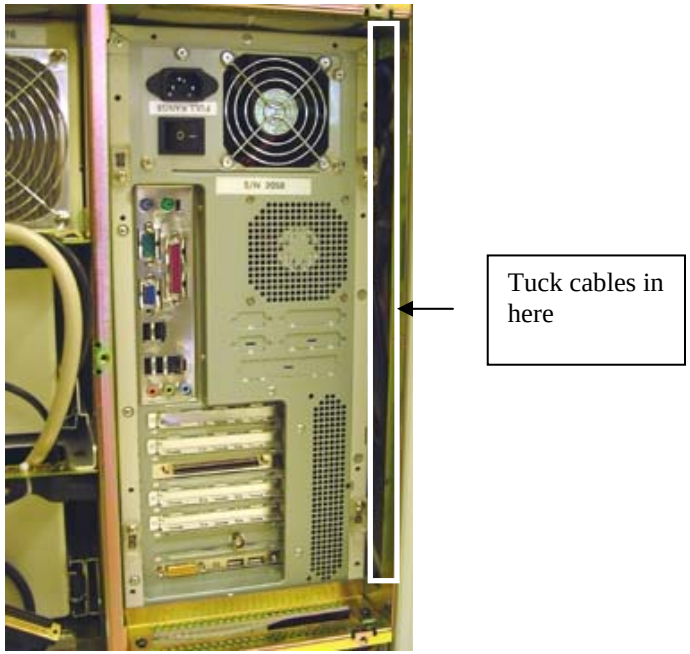
2.5 Thread the Framegrabber cable and the PC Power cable through the chassis assembly as shown.

2.6 If the system has a dye sub. printer then thread the cable through the chassis assembly as shown.

2.7 Remove the 2 screws holding on the bracket with the 3/32” hex wrench.



2.8 Tuck all other cables to the side and then pull out the computer.



2.9 Remove computer.

Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

3.0 Install replacement computer

3.1 Slide the computer half-way into the chassis.

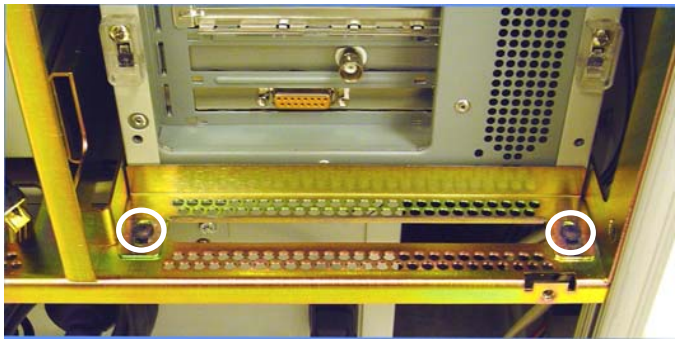
Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

3.2 From the front of the RetCam II system, inspect the left side of the computer and tuck in any cables sticking out.

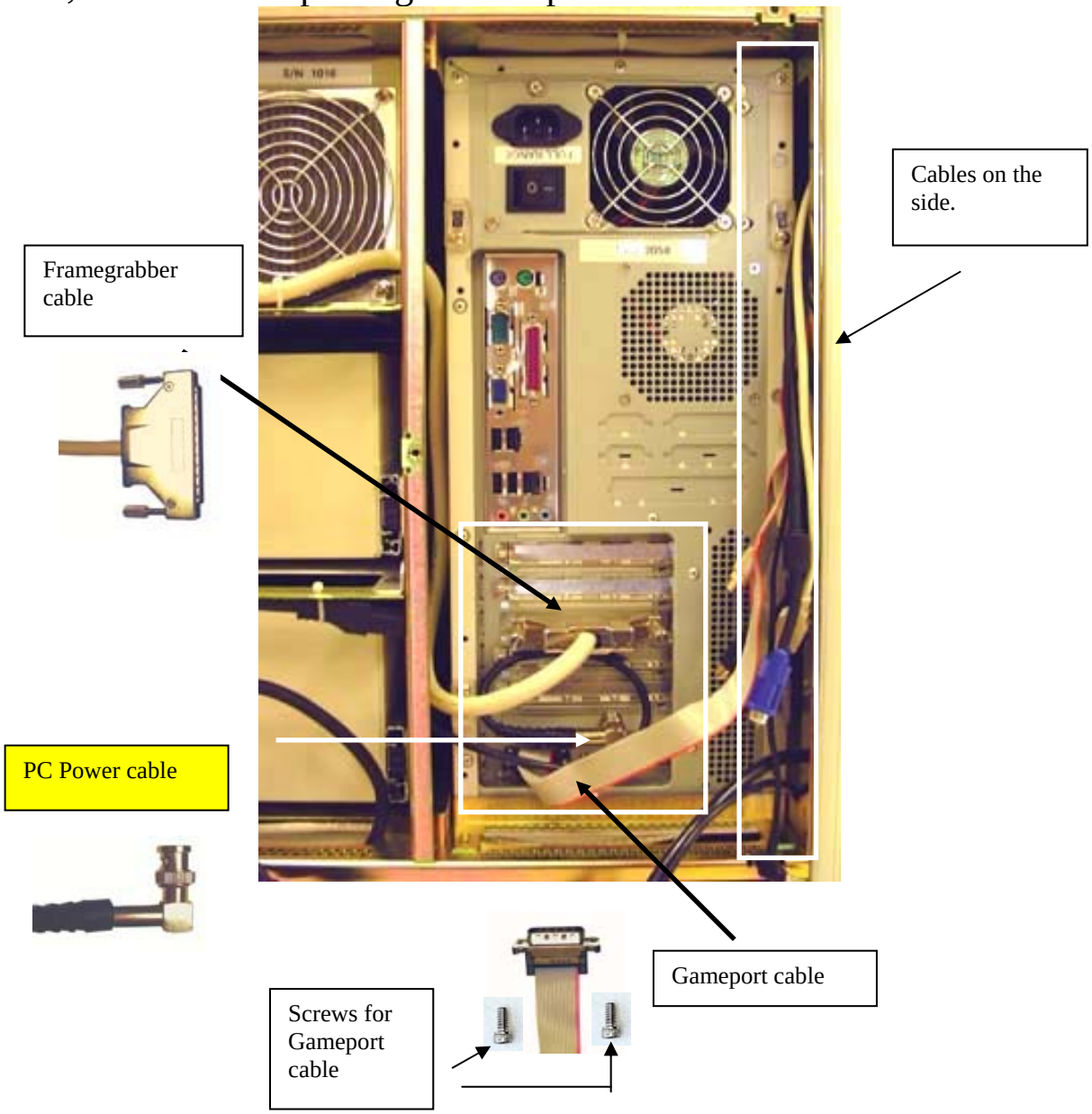
3.3 After the cables have been tucked in, slide the computer all the way into the chassis.

3.4 Secure the computer by attaching the bracket to hold it in place.



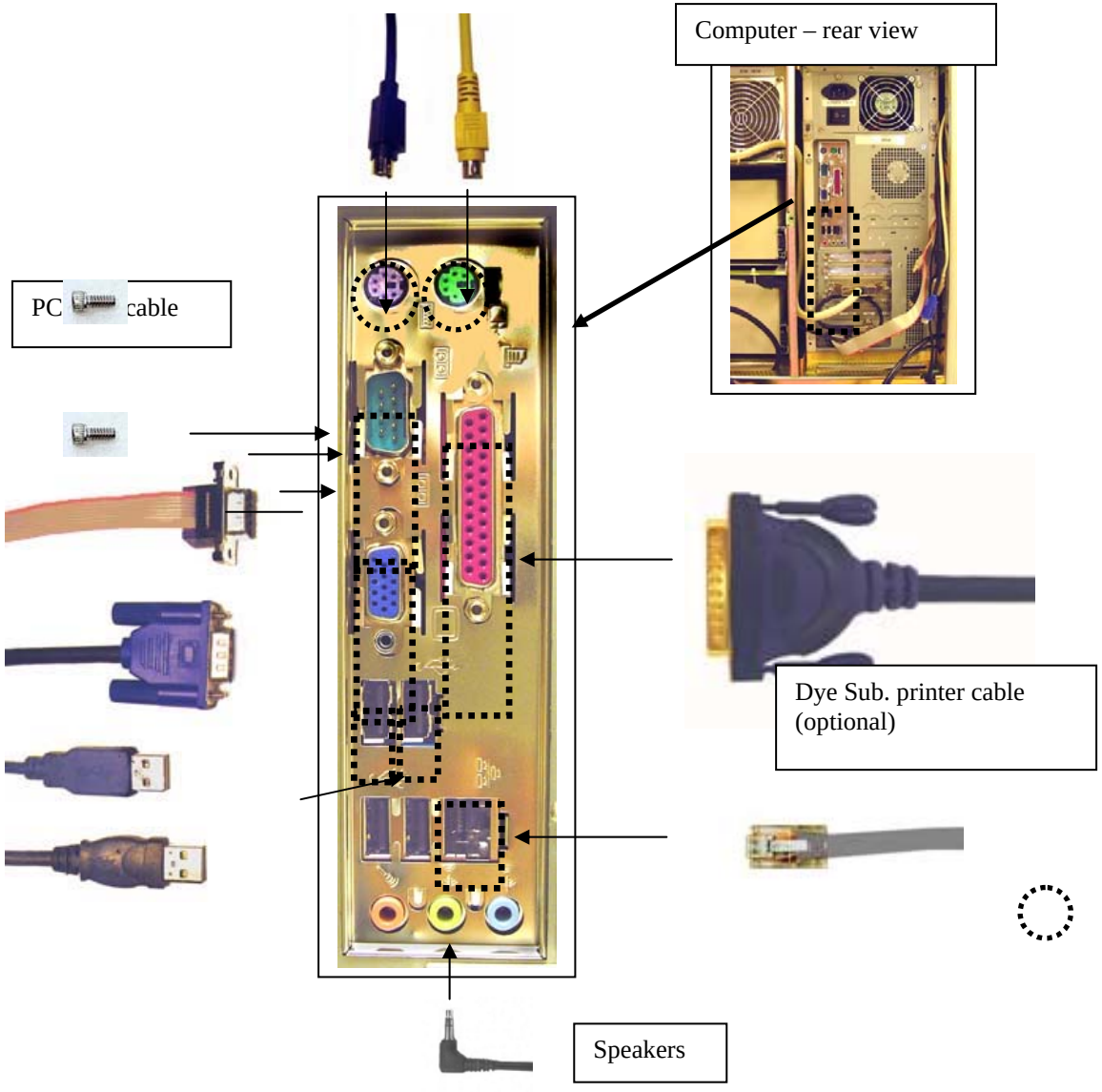
3.5 Pull the cables out of the side of the system and fasten the Gameport cable to the computer.

3.6 Attach the framegrabber cable and the PC Power cable.



3.7 Plug in the cables as shown:

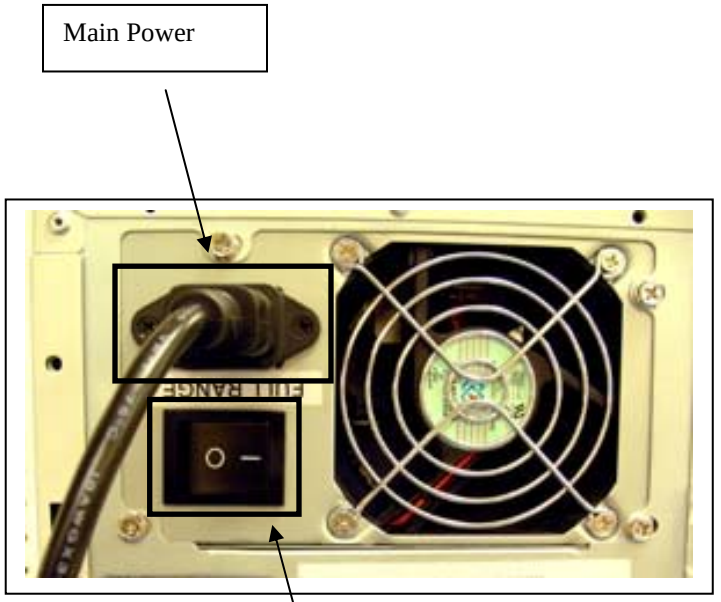
Keyboard
Trackball
Dye Sub. printer cable
(optional)
PC Com
(fasten with screws)
Display
USB printer
USB external extension
Speakers
RJ 45 Network cable



Service Method

800136, Revision A, Method for replacing the computer in the RetCam II

3.8 Plug in the main power to the computer.



3.9 Press the power switch to the on ‘ | ‘ position.

Service Method

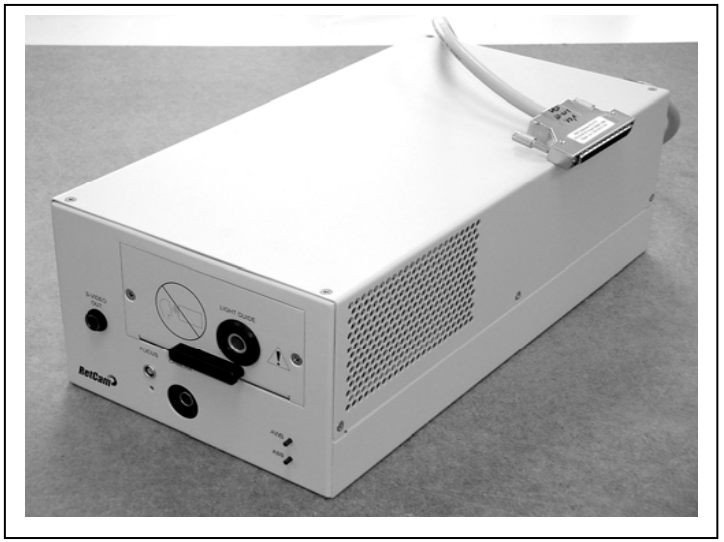
800136, Revision A, Method for replacing the computer in the RetCam II

4.0 Restore to the original condition.

4.1 Inspect workmanship and and verify cables will not be pinched when the rear panel is installed.

4.2 Fasten the rear panel to chassis.

4.3 Unlock the front casters.
4.4 Plug the system into the proper outlet.
4.5 Turn the system power on.



Rev	ECO	Revision History	Author	Date
A	2659	Initial Release	Calvin Meister	08/02/06

Method:

Replacing the lightbox
in a RetCam II

Equipment and Supplies:

Lightbox (PN 13-00-000)
Wire ties

Tools needed:

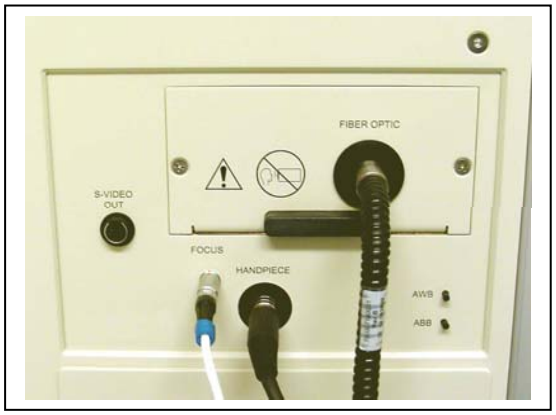
1/8” Hex wrench
3/32” Hex wrench
9/64” Hex wrench
Sidecutters (to cut the wire ties)

Outline:

1. Preparation.
2. Removal of Lightbox
3. Install the Replacement Lightbox
4. Restore to the original condition.
5. Return replaced lightbox in original packing material.

1.0 <u>Preparation.</u>

1.1 Turn the system power off.
1.2 Unplug the system from the outlet.
1.3 Lock the front casters.
1.4 Remove the 3 handpiece cables from the front of the lightbox. The fiber optic cable pulls out. The focus cable has a sleeve, pull out on the sleeve to remove the cable.
The handpiece cable has a sleeve that is threaded on the connector; unscrew the sleeve and then pull out the connector.
1.5 Remove the rear cover.
There are 7 screws holding the back panel to the system.
Using a 1/8” hex wrench remove these screws.



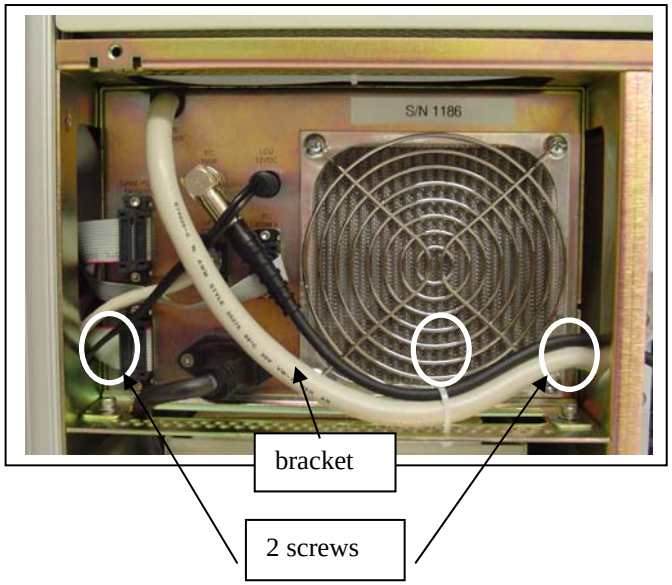
2.0 Removal of Lightbox

2.1 Cut the cable tie holding the lightbox cables to the frame.

2.2 Remove the 2 screws holding the lightbox bracket in place.

2.3 Disconnect the cabling to the lightbox and tuck in the side of the system.

2.4 Disconnect the lightbox framegrabber cable at the computer and thread through the frame.



2.5 From the front of the system, gently push the lightbox out the back and remove it for transport.

3.0 Install the replacement Lightbox

3.1 Clear the cabling from the lightbox slot and insert the lightbox into the RetCam II system.

3.2 Thread the Framegrabber cable through the frame and attach it to the Framegrabber card in the computer.

3.3 Thread the PC Power cable through the frame and attach it to the lightbox BNC connection.

3.4 Install the UPS Control connector.

3.5 Install the Gameport Trigger, PC Com X and Membrane harnesses and attach them to the connection standoffs with screw (PN 07-00-009).

3.6 Lift the power cord up through the frame and before inserting it into the receptacle install the bracket holding the lightbox in place.

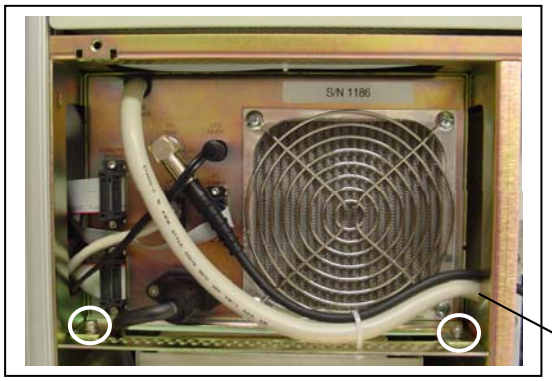
3.7 Attach the bracket to the frame.

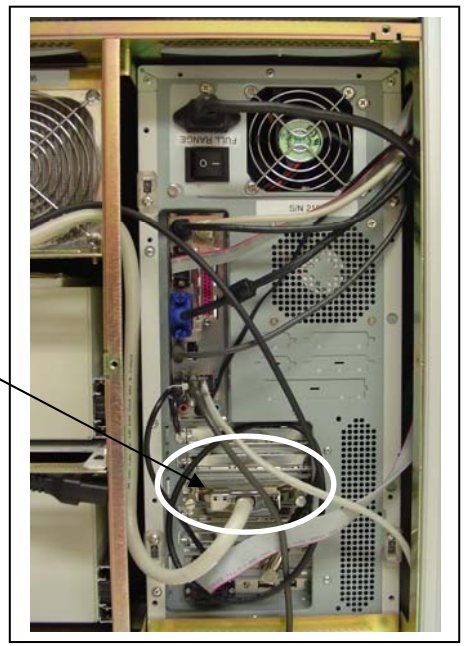
3.8 Insert the power cord into the receptacle.

3.9 Wire tie the Framegrabber and PC Power cables to the frame.

Cable not cleared

Cable cleared





4.0 Restore to the original condition.

4.5 Inspect workmanship and and verify cables will not be pinched when the back panel is installed.

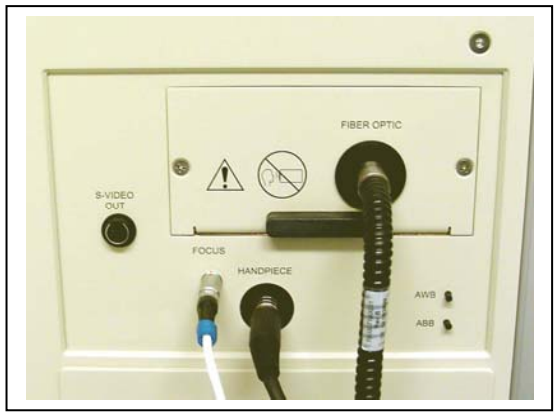
4.2 Install the back panel and fasten with seven flathead screws, 10-32 x .38" (PN 07-00-203)

4.3 Reattach handpiece cables to lightbox.

4.4 Unlock the front casters.

4.5 Plug the system into the proper outlet.

4.6 Turn the system power on.

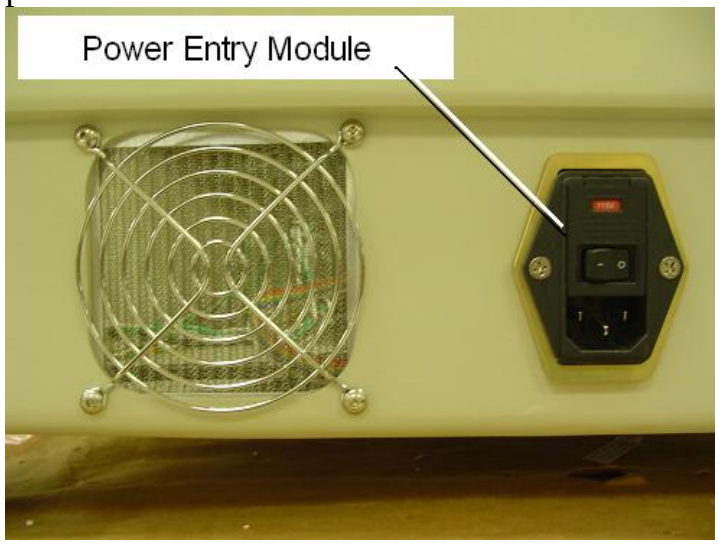


5.0 <u>Return replaced lightbox in original packing material.</u>

Appendix 9
Fuse Replacement

Locate the Power Entry Module on the rear side of the base console. Ensure the Power Cord is removed before proceeding any further.

Fuse Replacement



Power Entry Module

Use a flat blade screwdriver to open the Fuse Drawer located at the top of the Power Entry Module.

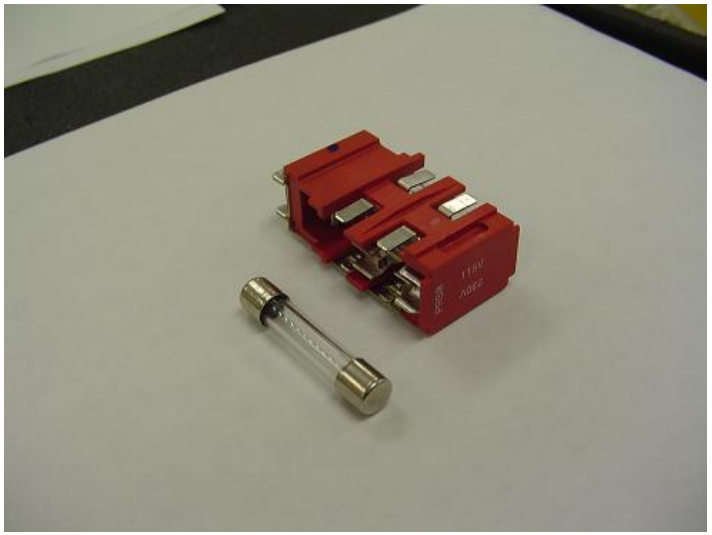
Opening Fuse Drawer

Fuse Replacement

Remove the Fuse Drawer.

Removing Fuse Drawer

Remove the damaged Fuse from the Fuse Drawer and replace it with a known good Fuse.



Damaged Fuse Removed

Appendix 9

Fuse Replacement

Re-insert Fuse Drawer into Power Entry Module. Observe the labeling on the front of the Fuse Drawer. The top and bottom of the fuse drawer are labeled with the proper input voltages for your System. Either (115 V) or (230 V). Insert the Fuse Drawer with the proper voltage being displayed at the top of the fuse drawer. After closing the door to the fuse drawer, the operating voltage should be visible through the window in the fuse drawer.

Fuse Drawer Re-Inserted

Operating Voltage Visible Through Window

CAUTION: Do not touch the bulb located in the center of the reflector, or the concave surface of the reflector. Skin oils will adhere to the outside of the bulb, reducing the cooling efficiency of the bulb, creating a hot-spot and subsequent premature burnout. Handle by the reflector only.

Appendix 10

Changing the illumination bulb

The illumination light bulb located in the Light Box will need periodic replacement. It is a 12 volt, 75 watt halogen bulb, industry type EKE. Replacement bulbs are available from Customer Service.,

1) Shutdown the RetCam II according to the user manual, if it is not already turned off.
2) Disconnect the main power cord from the wall.
3) Unplug the fiber optical cable from the front of the Light Box.
4) Remove the two screws from the small front panel.
5) Grip the handle on the small panel. Pull the small front panel out slowly from the Light Box. Stop when the light bulb is fully exposed.
6) Remove the illumination bulb from the socket and replace it with the new one.
7) Check the position of the new bulb to make sure that the reflector of the bulb is located in the center of the lamp socket's opening.
8) Push the small front panel back into the Light Box slowly. Use caution to avoid pinching wires in the area.
9) Replace the two screws on the small front panel.

Rev	ECO	Revision History	Date	Approved
A	2356	Release, CTI keyboard	2004	G. Sprehn
B	2532	Input Technologies keyboard	09/12/2005	G. Sprehn

Method 800095 Revision B, Keyboard replacement

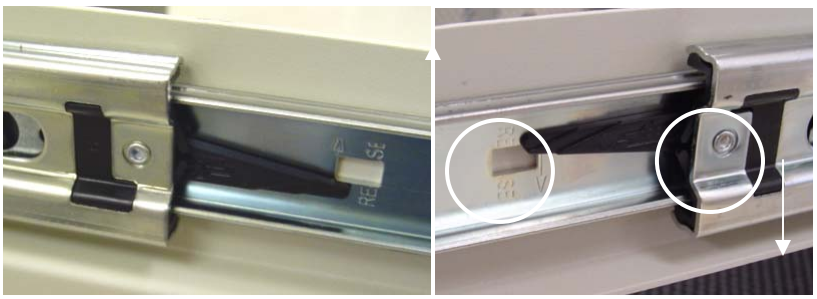
Procedure:	Replacement of keyboard in the RetCam II imaging system.
Contains:	Listing of tools and supplies along with step by step instructions on the replacement of the keyboard.
Tools:	Hex wrenches – 3/32 and 5/64 inch Philips screwdriver - #2 Ratchet and socket or nutdriver – 5/16 inch Sidecutters (wire cutters for cable ties)
Supplies:	Drawer liners – in printer and front storage drawers. Nylon cable ties – standard 4” or more length x .10” width

Outline: 1.0 Removal of keyboard.
2.0 Installation of keyboard.

1.0 Removal of keyboard.

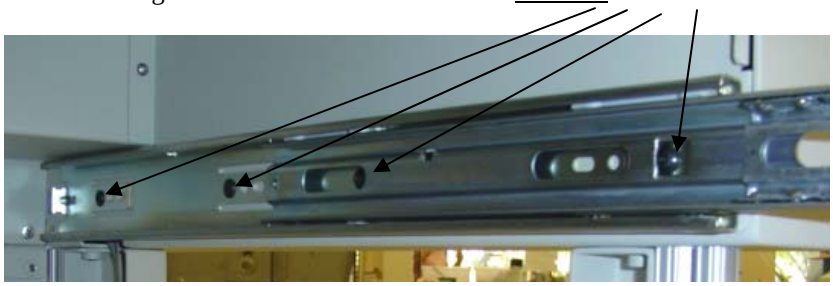
1.1 **Disconnect the power cord at the back of the base.**
1.2 Open the printer drawer and disconnect the power and USB cables from the printer.

1.3 Lift the printer out of the drawer.
1.4 Remove the printer drawer.
1.4.1 Extend the drawer fully open.
1.4.2 Locate the black locking tabs on both sides of the drawer gliders.
1.4.3 Pull the left tab upward and the right tab downward as you pull the drawer out of the system.

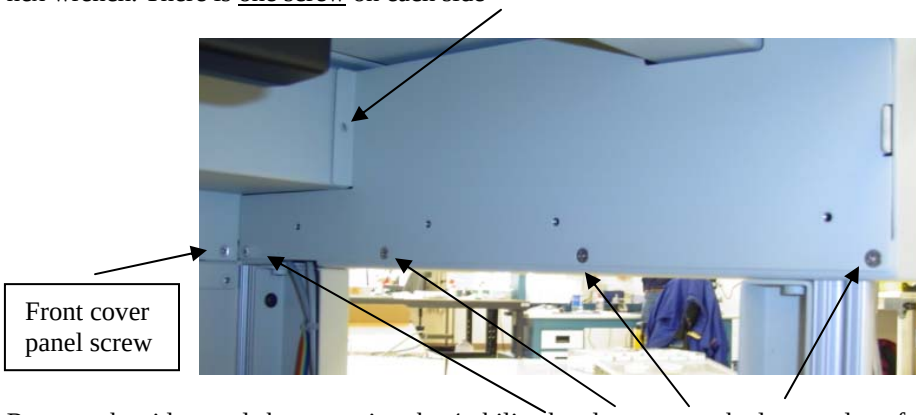


1.5 Place drawer liners inside the RetCam II chassis to prevent screws removed from falling down. Use the liners from the printer and front storage drawers.

1.6 Remove the glider tracks from the inner panels on the system.
1.6.1 Extend the gliders as necessary to expose the screws.
Using a 3/32 inch hex wrench remove 4 screws from each side.



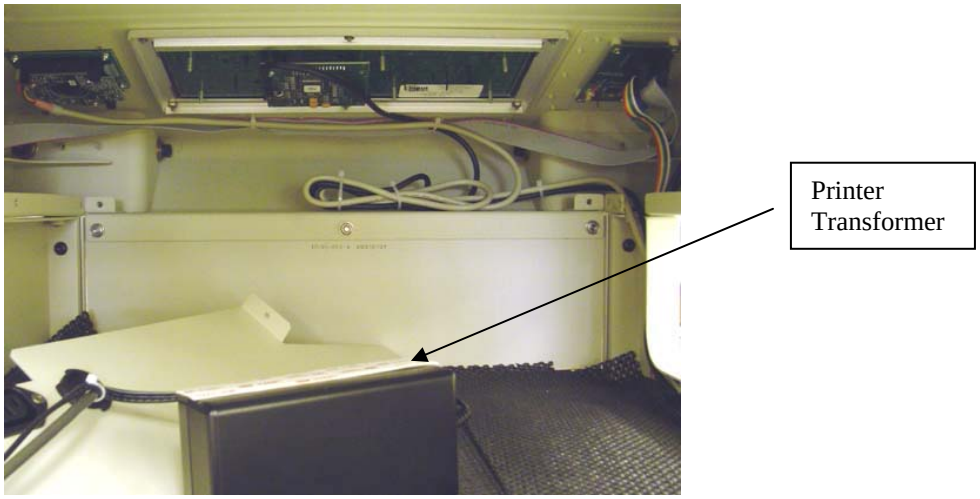
1.7 Remove the upper screws securing the side panels to the front cover using a 5/64 inch hex wrench. There is one screw on each side



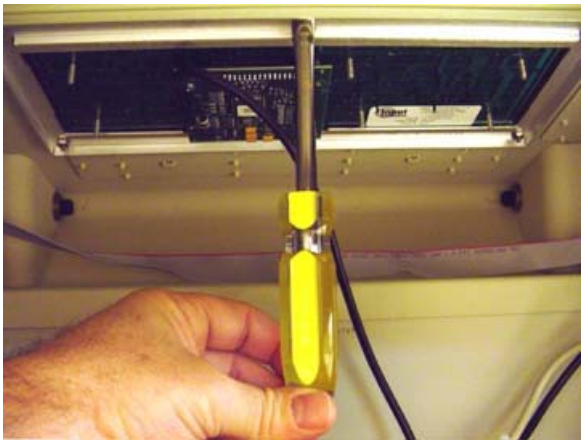
1.8 Remove the side panels by removing the 4 philips head screws on the lower edge of each panel. The panel on the left has cabling attached,
lower this out of the way.

1.9 Remove the front cover panel by removing the 2 philips screws located on the lower corners of the panel.

1.10 The printer power transformer is attached to the underside of the top panel with thick tape. Gently pry this loose and set it aside.



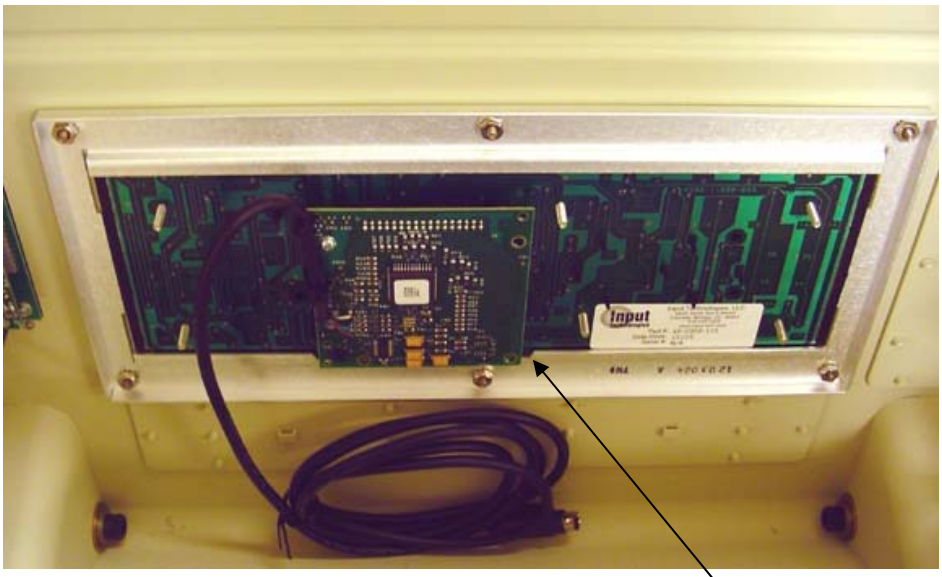
1.11 Remove the nuts securing the keyboard frame to the chassis with the 5/16” nutdriver.



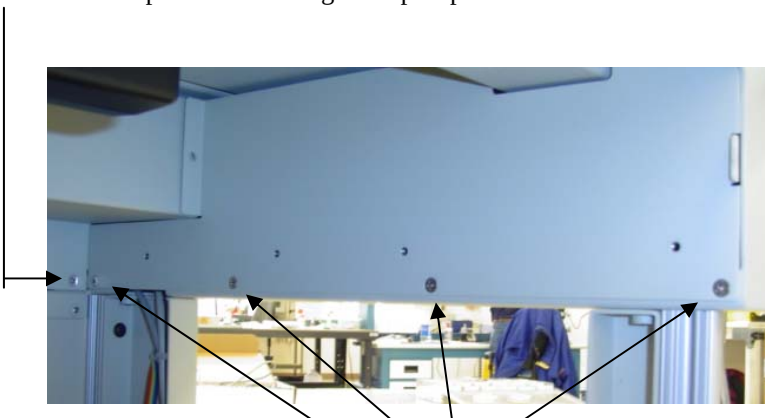
1.12 Cut the wire ties routing the keyboard cable and unplug the keyboard cable from the computer.

2.0 Installation of Keyboard.

2.1 Remove the keyboard from the packaging.
2.2 Mount the frame around the keyboard and attach to the chassis.



2.3 Route the keyboard cable to the computer and connect it.
2.4 Wire tie the keyboard cable to the RetCam II chassis.
2.5 Install the front panel cover using the 2 philips screws.



2.6 Install the side panels using 4 philips screws each.

2.7 Secure the 2 hex screws holding the side panels to the front panel.

2.8 Install the side glider tracks.
2.9 Resecure the printer transformer to the underside of the top cover.
2.10 Remove the drawer liners.
2.11 Install the printer drawer.
2.12 Connect the power and USB cables to the printer.
2.13 Connect the power cord to the system and verify the power switch on the base is turned on.

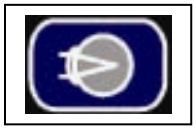
RetCam Handpiece Focus Method 800138, Revision A

Rev	ECO	Revision History	Date	Approved
A	2549	Release	October 5, 2005	G. Sprehn

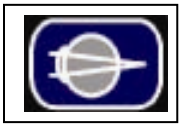
1. This service method applies to RetCam 120 and RetCam II, all white handpieces.
2. If the handpiece doesn't make a soft motor sound when the focus buttons are pressed, troubleshoot the electrical problem first.
3. The simplest way to troubleshoot a focus problem is to operate the handpiece without any lenses attached.
4. Pull the fiber optic cable only from the lightbox (focus to the room lighting). With a live image on the screen, find the distance at which a target (business card, zip disk, cotton swab, finger) is in focus. Measure or estimate the distance from the front surface of the camera.
5. The total range of focal distance is -0.15" (– 4 mm) which is just inside the front surface, to 3.3" (approximately 85 mm) from the front surface.

On the RetCam II system

To move the focal distance closer, press the left membrane 'focus closer' button.



To move the focal distance further, press the right membrane 'focus further' button.



6. [For RetCam 120 only, press the rocker switch on the light box in the up position to focus closer, and the down position to focus further. It is preferred to use the rocker switch on the light box because the footswitch alternates direction.]

7. The focal distance in this configuration to preset for use with an ROP D1300 or Children's B1200 lens used for imaging the retina is approximately 24 mm (1"). The focal distance to set for imaging the anterior segment is approximately 12 mm (0.5").

8. It takes approximately 62 seconds for the focus motor to travel the full range.

9. It takes approximately 13 seconds to go from retinal to anterior imaging, holding the 'focus closer' button. Conversely, it is approximately 13 seconds holding the 'focus further' button to go from anterior segment back to retinal imaging.